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Food Safety and Government Regulati...

S. HRG. 103-108

FOOD SAFETY AND GOVERNMENT REGULATION OF COLIFORM BACTERIA

HEARING

BEFORE THE

SUBCOMMITTEE ON AGRICULTURAL RESEARCH, CONSERVATION, FORESTRY, AND GENERAL LEGISLATION

OF THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

NEED FOR CHANGES TO FEDERAL FOOD INSPECTION PROGRAMS TO ENSURE MEAT IS SAFE FOR CONSUMERS

FEBRUARY 5, 1993

Printed for the use of the
Committee on Agriculture, Nutrition, and Forestry

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CONTENTS

FOOD SAFETY AND GOVERNMENT REGULATION OF COLIFORM BACTERIA

FRIDAY, FEBRUARY 5, 1993

U.S. SENATE, SUBCOMMITTEE ON AGRICULTURAL RESEARCH, CONSERVATION, FORESTRY, AND GENERAL LEGISLATION OF THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,

Washington, DC.

The subcommittee met, pursuant to notice, at 10:34 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Thomas A. Daschle (chairman of the subcommittee) presiding.

Present or submitting a statement: Senators Leahy, Daschle, and Craig.

Also present or submitting a statement: Senators Murray and Gorton and Representative Dunn.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. This hearing will come to order.

I welcome everyone and thank the committee and the witnesses for their indulgence, given the short notice of this morning's hearing. It is critical to develop a public record on the circumstances and policy questions relating to this matter as soon as possible. I am grateful for the willingness on the part of those here today to come to the table for an open and frank discussion.

We will determine the extent of the problem our Nation faces from *E. coli* 0157:H7 and what changes to Federal food inspection programs should be made to ensure safe meat for American consumers. Through our work today and in coming weeks, we must join together to ensure that something like this will not happen again. For the sake of our children and the confidence of their families, we must continue to have the safest food supply in the world.

On Friday, January 22, 1993, 2-year-old Michael Nole of Tacoma, Washington, died of food poisoning attributed to an infection contracted from *E. coli* 0157:H7 after eating a hamburger at a Jack In The Box restaurant in Seattle, Washington. Soon thereafter, 2½-year-old Celina Shribbs of Lynwood died of a secondary infection after contracting the disease. Still in critical condition is 10-year-old Sara Brianne Kiner, and 16-month-old Riley Detwiler. There are 17 patients at Children's Hospital and Medical Center in Seattle, with 7 on kidney dialysis machines and the rest in satisfactory condition as of last night.

There is no conventional treatment for the infection caused by *E. coli* 0157:H7. It is a relatively new and particularly viral strain of *E. coli,* and it is believed to be responsible for the outbreak that has affected at least 348 people in Washington, and more in Idaho and Nevada. Given the critical nature of this health matter, it is of the utmost importance that concrete steps be taken as soon as possible. Let us learn from this tragedy, so that we do not repeat it.

In response to the outbreak of food poisoning, President Clinton dispatched Secretary Espy to Washington State to investigate the situation. I am grateful to the President and to Secretary Espy for their prompt personal attention and action.

It is my understanding that Secretary Espy will be presenting several ideas for us to explore as options for resolving this crisis, and while our system of government is known for moving at glacial speed, the rapid response of Secretary Espy is a welcome sight. I look forward to working with the new administration and the new Department of Agriculture.

Our food inspection system relies chiefly on visual inspections, which manage to detect feces, blood, damaged carcasses, bone fragments and other contaminants, but allow microscopic pathogens to escape detection. The system relies on a scoring of contaminants both on an individual and aggregate level. Put simply, a certain number of hairs, bone fragments, or amounts of blood or feces will prevent a carcass from being processed.

While the inspectors in this case worked within the system and performed responsibly, standards are inadequate or non-existent for bacterial contamination and must be strengthened. The Food Safety and Inspection Service believes that the *E. coli* pathogenic bacteria were introduced into the food supply prior to processing. Blocking entry of contaminants into the food supply prior to processing will require more stringent inspections at the source.

Blocking contamination at the source is not fail-safe and is not the complete solution. The Centers for Disease Control noted that food obtained from unsafe sources was the least reported factor in foodborne illnesses between 1983 and 1987. In cases where cause could be determined, 92 percent were due to food handling practices—usually storing at improper temperatures or poor personal hygiene of food handlers. We must work to further strengthen all aspects of food safety, from the farm to the refrigerator to the stove.

The FSIS and the Food and Drug Administration consider the Hazard Analysis and Critical Control Point, the HACCP system, to be the most effective strategy for controlling the presence of pathogenic bacteria, including this strain of *E. coli.* I am hopeful that the witnesses will give us their opinions about implementing this type of bacterial control program into our food safety inspection system, and I hope they will tell us exactly what they believe should be included in such a science-based risk assessment system.

While most of us cannot begin to fathom what the families of Michael Nole and Celina Shribbs are going through, I can certainly understand the anger that they must feel at what has been for too long an unresponsive Government. Change in the inspection system is long overdue. For several years many of us on this committee have advocated augmentation of the meat inspection process

with a bacterial detection system. At a hearing held by this subcommittee in 1989, it was clear that such a system was necessary. [1]

Sadly, it seemed then that those who opposed change held the cards.

After decades of neglect on food safety regulation, our children continue to pay the price, and that is unacceptable. This subcommittee will work diligently with the President and Secretary Espy on whatever legislative or regulatory changes that need to be made to contain, identify and eradicate harmful bacteria in the food supply.

We must also recognize, and emphasize, that a major share of the responsibility for safe food must be shouldered by food handlers and preparers. Inspection and eradication during processing will not solve the problem, regardless of what changes we propose. Only in concert with far more effective handling and cooking standards for meat products will we realize true success.

Before calling on the Secretary for his testimony, let me ask my colleagues if they have any opening statements they would care to make, and I begin by calling upon our chairman, Senator Leahy.

STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

The CHAIRMAN. Thank you, Mr. Chairman. I commend you and Senator Craig, the ranking minority member, for holding this hearing. It is extremely valuable. It allows me to do publicly what I did privately in a meeting earlier this morning with Secretary Espy—commend him for the way he is handling this outbreak of foodborne illness.

Mr. Secretary, it occurred four days before you were sworn in as Secretary. You became Secretary and immediately you flew to Washington State to look into this matter yourself. You didn't send somebody else to report back to you; you went yourself. It sends a powerful message, and I know you intend to offer a plan to help prevent these types of outbreaks in the future.

I was impressed, too, in your private comments to me, with your concern for those who suffered through it. And, Mr. Chairman, I know that you, too, empathize with the children and their families who have suffered through this. As a parent, I can well imagine what the families are going through.

For too long the Department has hoped these problems would go away. We need a positive force to show not only will they not go away, but they need addressing. We don't need another report on food safety. We need action on food safety. Twelve Federal agencies spend about $1 billion annually to administer 35 separate laws regarding food safety and quality. Are we getting our money's worth?

The Department of Agriculture in many areas is using inspection techniques that were developed in the early 1900s. It is time to bring the inspection process into the 1990s. We need improved microbiological testing for contaminants. We need improved slaughtering and inspection processes to minimize the risk of these outbreaks.

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[1] Scientific Base for Food Inspection, Subcommittee on Agricultural Research and General Legislation, July 20, 1989 (S. Hrg. 101-916).

I look at this not only as chairman of the committee, but also as a parent. Two children have died and one is gravely ill; a 4-year-old girl has had a stroke. This is someone whose whole life is ahead of her. We must prevent these problems from occurring in the first place. I am very eager to see what comes from the chairman of this subcommittee, Senator Daschle, who is as well equipped as any member of the Senate to be looking into this problem.

Mr. Secretary, if you need more legal authority to prevent these problems, just let us know. We will move very quickly here in the Congress to help you. I think you need to work toward a science-based risk assessment inspection system across-the-board. The National Academy of Sciences favors a system that would be based on public health risk. USDA has admitted it needs to be done. It has not been done, and I hope that you will have a chance to make sure it is done.

E. coli 0157:H7 survives refrigeration. It also survives freezing, and very low numbers of it can produce infections. It is lethal and it preys on the most vulnerable in our society—young children, the elderly, and people who are already ill. It can cause acute kidney failure, seizures, coma, and death. It was first reported in ground beef in 1982 and, since then, 16 deaths have been linked to it.

A 1986 outbreak in Walla Walla, Washington killed 2 persons and hospitalized 17. The State of Washington very commendably raised the required cooking temperature to address that problem. Yet this latest outbreak, caused by the same pathogen, was worse and again deadly.

Thorough cooking is an answer—but it is not the complete answer because errors are made. This happened once before. Temperatures were raised; seven years later, it happens again. Children are going to continue to eat in restaurants and children do not bring meat thermometers with them to restaurants. Parents make mistakes also, but the death penalty is too strong for a cooking error. We would all agree on that.

We need to change the underlying system. We need to make structural changes and allow food safety controversies to be resolved based on sound science. I am not a scientist. You and the people in your Department are the ones who can give us the answers. We stand ready to help you implement them.

Again, Mr. Chairman, I applaud you and your ranking member for having this hearing.

Senator DASCHLE. Thank you very much, Mr. Chairman. I now call on the ranking member on the subcommittee, Senator Craig.

STATEMENT OF HON. LARRY E. CRAIG, A U.S. SENATOR FROM IDAHO

Senator CRAIG. Mr. Chairman, thank you very much, and I am pleased to have the chairman of the full committee with us this morning. Secretary Espy, thank you for your responsiveness in coming before the subcommittee.

We all know about the tragic incidents that gave rise to this hearing. They have been vividly portrayed in the news across the country and it has brought a new public awareness this concern. You have arranged a broad group of competent individuals, Mr.

Chairman, who I hope will help this subcommittee and the Congress gather the information that will help us understand what happened, how, and why.

We, the Congress, can and should have all the facts before we attempt to do anything, such as mandating some action by Federal, State or local entities of government. It is important for the record to show that this is not solely a Federal responsibility, as evidenced by the reaction and action, in this case, of Washington State government, and over the years, other State governments, as they share in this responsibility with local units of government in areas of inspection.

It is imperative that we acknowledge for the witnesses as well as those who may be present or may review this record that this is not a court of law. We are not here to establish guilt or innocence. There will be plenty of time in the appropriate forums for that.

What do we need to accomplish from this hearing and Congressional review of the problem? First, we need to find out why it happened to ensure, if possible, that it doesn't happen again. Clearly, the American people must understand that their food is safe, and that requires information. We are here to get that information.

Much has been said about what has happened and why it happened. It is a great tragedy, and the chairman properly reflected our concern for our young people. I am concerned for anyone who might eat improperly prepared food that would cause them tragic illness and/or death.

I look forward to hearing the witnesses and what they have to tell us. It is impossible to remove all uncertainties. This is not a zero-sum game. There may be legitimate needs and effective uses of chemicals to avoid such cases as the ones that we address here today, and maybe other processes should be involved.

We all have a personal responsibility to understand the dangers in the preparation of food under our control and how to correct them. This is not solely the responsibility of Government. Government does, though, have a responsibility to ensure the public is informed either directly by Government agencies or indirectly by the private sector.

We must note that Government has a legitimate responsibility to monitor those areas where the public generally operates, but has no direct control. In short, the public deserves and must have assurance of the safety of food. I argue that almost all food today is safe, and it is under that understanding that our public approaches food with relative innocence.

I have some general questions at the beginning of the hearing and ask if all of the witnesses would address them in general or specifically from their individual perspectives. It is valuable that we all hear these questions.

What is the correct process? How does meat get from the hoof to the hamburger? What happens? How did this happen? What are the Government standards and inspection requirements that ensure compliance with requirements in this process?

We have inspectors and standards in various phases of the process—slaughter plants, transportation between slaughter and processing plants, transportation to the eating establishments, storage

at the eating establishment and preparation at the eating establishment.

When does it happen? How is the process monitored, and who is responsible for that monitoring, Federal, State and local government agencies, and which phase and when? What are the safeguards currently in place to ensure public safety? There are many. Are those safeguards, inspections and standards adequate?

After we get all of the information, we have to decide if the process is adequate and, if not, how can we improve it. Our Secretary is already beginning to make some recommendations. What options are viable under good science practices? We must not mandate something that is scientifically impossible to achieve.

What remedies reasonably have a chance of improving the process? I hope we will not mandate something just to satisfy public concern that won't address the real issue. For example, mandating more inspectors who do not have the capacity to see contaminants simply would not address the problem.

Can Government agencies administratively address the issues? Can this be done more quickly? Do the agencies need more authority? Are there rigidities, both political and otherwise, that are built into the inspection system that some argue do not allow outsiders to enter into the process? I mean the rigidities that have existed for decades within labor unions which have kept certain activities from going forward. Do we have to attack that problem? If we do, we should. Does every agency have the authority that it needs? Do we need to consolidate agencies? As our chairman said, do you need more law, Mr. Secretary?

More research is needed to find where this problem can be most effectively addressed in the food handling chain. More research is also needed to find an antidote for this toxin.

Mr. Chairman, again, thank you for scheduling this hearing. I look forward to an informative session. You have brought together the people most knowledgeable in the area. I will be spending the morning listening and questioning and hoping we can build a responsible and effective record.

Thank you.

Senator DASCHLE. Thank you very much, Senator Craig. We are pleased to have both of our Senators from Washington State sitting in on this hearing with us this morning, and I welcome them and invite their comment.

Senator Murray.

STATEMENT OF HON. PATTY MURRAY, A U.S. SENATOR FROM WASHINGTON

Senator MURRAY. Well, thank you, Mr. Chairman, and thank you from the bottom of my heart for having this hearing and for allowing this issue to be here in front of us so we can investigate it and move on. I have heard from numerous of my constituents who are frightened and scared, and I can tell you that public confidence has really eroded in my hometown of Seattle.

Parents who routinely take their kids to fast food restaurants are not doing so. There are 400 children and thousands of parents who should not have been affected by this crisis, and I really appre-

ciate the opportunity you have given us by having this hearing. I also thank you, Mr. Secretary, for taking such immediate action on this. I am very anxious to hear what your thoughts are on this and where you think we should proceed.

I do have a prepared statement I would like to submit for the record, but let me just quickly focus on two concerns I hope that you address. One of them is the visual inspection process that is done under FSIS. I understand that an inspector has only eight seconds to look at a side of meat before it moves on. In addition, there are no microbiological standards or testing that is done even though that information is available for *E. coli,* and I want to know how we can look at doing that and if that is part of your recommendation.

I also hope that you focus on the meat temperature problem. There is a model standard out there, but every State has its own guidelines. Should we be looking at Federal guidelines and mandates?

There are many issues that my colleagues have brought before us that I hope we hear you address, but I want to reemphasize this is not a small problem. It is not something that we can just have a hearing on and then move on. Four hundred people are being affected immediately, but I also understand that 280,000 hamburger patties were contaminated. That is a tremendous amount of hamburgers. Fortunately, the State of Washington Public Health Department was able to stop most of that, but it concerns me as a parent, and it concerns many of my friends and family at home.

I am very anxious to hear what you have to say, and I thank you for looking into this.

Senator DASCHLE. Thank you, Senator Murray. Without objection, your statement will be made part of the record.

[The prepared statement of Senator Murray follows:]

PREPARED STATEMENT OF HON. PATTY MURRAY, A U.S. SENATOR FROM WASHINGTON

Mr. Chairman, I commend you for calling today's hearing. As you are well aware, we have a tragic situation in Washington State. At least 335 people in my home State of Washington, and many others throughout the Western States, have contracted disease stemming from the bacteria *E. coli.*

This disease has been traced to contaminated meat served by a fast food restaurant chain. Of the hundreds of people afflicted by *E. coli,* many are children, Mr. Chairman. I am especially saddened by the deaths of the two children, and want to extend my deepest sympathy to their parents and families.

Mr. Chairman, at issue here is the basic safety of the public's food supply. When parents put food on the table, they shouldn't have to worry about whether it is good or bad. The Government should already have taken care of that, leaving parents free to meet their family's needs or share a little quality time. This is how it should be.

It is a gross tragedy—and a failure of Government—when it takes two deaths and hundreds of serious illnesses to bring a problem to the public's attention. This reminds me of Upton Sinclair's novel, "The Jungle," about the slaughterhouses in Chicago at the turn of the century. Something is seriously wrong with our Government's priorities.

The policies pursued over the last 12 years concern me, especially Federal meat inspection and cooking guidelines for restaurants.

The Food Safety and Inspection Service (FSIS) within the USDA has responsibility for inspecting meat. In the last decade, FSIS has emphasized corporate quality control efforts. This means the agency has taken its own inspectors out of the plant and relied on company personnel. Inspections are done on a visual basis, and the average inspector has eight seconds to determine whether beef is acceptable. Given the latest crisis, I'm not sure this is wise.

FSIS has neither microbiological standards governing acceptable meat products, nor any laboratory testing capabilities to identify bacteria in meat. More worrisome, it appears that the agency under the two previous Republican administrations explicitly rejected research and recommendations underscoring the need for such standards. In spite of the efforts of the National Academy of Sciences and food inspection workers, USDA has consistently ignored the need for tougher inspection standards.

Once meat enters a restaurant, the Food and Drug Administration bears responsibility under the Public Health Service Act for assisting States in developing requirements that will ensure restaurant food is safely prepared and served. In attempting to meet that responsibility, FDA has formulated a "model retail food code" that establishes minimum cooking temperatures to prevent bacterial infection. As I understand it, this code is not binding; rather, it is advisory.

Several things worry about me about this. First, in the absence of a binding Federal standard, we have been left with up to 50 separate sets of regulations governing food preparation in this country.

Second, the FDA model may not be sufficient. In my State, the health department deemed FDA's standard too low and set a minimum cooking temperature 15 degrees higher. Even that wasn't enough to protect consumers.

Mr. Chairman, there are several Federal agencies involved in this chain, and it seems their respective actions aren't complementary, or even coordinated. Somewhere along the line, the system broke down. We now question the basic safety of the public food supply. We in the policy-making branch of Government must waste no time in seeking corrective measures.

Again, I commend you for calling this hearing, and I stand ready to work with you and Secretary Espy to do everything we can to restore people's confidence in their food at both restaurants and at home.

Senator DASCHLE. Senator Gorton.

STATEMENT OF HON. SLADE GORTON, A U.S. SENATOR FROM WASHINGTON

Senator GORTON. Thank you, Mr. Chairman. Just a very few weeks ago, almost no one living in the State of Washington knew what the phrase *E. coli* 0157:H7 meant. They have now learned what it means, very much to their regret, as have people all across the country. We have had two deaths, several hundred illnesses, including serious hospitalizations, and each one of those, of course, represents a discreet individual, the member of a family, personal heartache and personal agony. So what we are here to do today is to determine how to prevent this kind of individual and community tragedy from taking place again.

As Senator Craig said, this isn't a judge and jury with respect to individuals or restaurant chains. It is a Congressional subcommittee to determine the first step of legislation, if legislation is needed, to improve meat inspection standards.

Mr. Secretary, I am sure that you would have preferred in your first week in office not to be faced with such a high-profile challenge and tragedy, but it is just because of that very real and human preference that we owe you such a debt of gratitude in taking a deep personal interest in it. We in Washington State thank you for going to our State and discussing this matter with our State legislators. We thank you for coming up with a number of ideas for food safety and inspection reform and for reassuring people. That is a wonderfully human start for your tenure in this office, and I and all of us in Washington State are grateful.

You know what an awesome responsibility it is to ensure the safety of our Nation's food supply, and we look to you for your specific recommendations. We have learned that the responsibility to

ensure meat safety is a burden shared by restaurant workers, individuals in home kitchens, processors, wholesalers, and the like, and that we need to cook at 140 degrees temperature or more.

We also know that these responsibilities won't be carried out by every individual, in every one of these chains and in every single set of circumstances. We have a lot of variables and a lot of risks, and if we could reduce those variables and risks, we would be doing very well.

I hope that you will comment on one system which we have known for many years, but which has been held up by controversy—food irradiation. It raises a whole series of additional questions, I know, but USDA should look at that alternative, as well as other alternatives, as it studies this problem.

We focus on food safety here today. Mr. Secretary, I am anxious to hear what you have to tell us and how you advise us to move.

Senator DASCHLE. Mr. Secretary, we again express our gratitude to you for the work you have done and for your willingness to come before the subcommittee this morning. We note for the record that Dr. Cross, the Administrator of the Food Safety and Inspection Service, is at the table with you. We are pleased to take his testimony in concert with yours and we invite you to proceed.

STATEMENT OF HON. MIKE ESPY, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Secretary ESPY. Senator Daschle, I appreciate the opportunity of appearing before you and your subcommittee today to discuss solutions to this tragic outbreak of foodborne illness in several Western States. I appreciate the opening comments of the chairman of the full committee, Senator Leahy, and those of the ranking member, Senator Craig.

Senator Craig, you have asked many questions of us here this morning. I have been on the job about 15 days. I won't be able to answer all of them, but I think——

Senator CRAIG. We will give you 15 more. [Laughter.]

Secretary ESPY [continuing]. Thank you. We can make a substantial start here this morning to alleviate the concerns we share about this tragic situation. And to both Senators from the State of Washington, Senator Murray and Senator Gorton, I wish that there could have been another reason I would have had a chance to travel to your beautiful State, but we had to jump on this because assuring and reassuring the safety of the food supply is a very important part of what we do.

I particularly welcome the willingness of this subcommittee to work in partnership with us to improve the meat and poultry inspection program. I think we all agree that changes must be made.

There are several reasons why I wanted to be here today. First, I want to express the deep sadness and concern that we all feel in the Clinton administration and at USDA about the deaths and illnesses that have occurred due to this outbreak of *E. coli* 0157:H7. As a parent, as a consumer, and as a former director of a State consumer protection authority, I well understand the fears and anguish that this has caused. Now, as the Secretary of Agriculture, I

pledge that I will devote every possible resource to containing the outbreak and work to prevent future ones.

Second, as all of you know, I did travel to the State of Washington earlier this week at the request of our President. The mission had been upgraded to the status of a Presidential mission, and all of you know what that means with regard to resources and availability of the Office of the President. It shows the concern that he has for the victims.

I had a very productive meeting while I was there with Governor Lowry, at which I relayed the deep concern of this administration. I am very encouraged by the excellent cooperation between the Federal, State and local authorities in dealing with this tragic event. The Governor and I also discussed the steps the State and Federal governments have taken and will take to control this outbreak in the short term.

I also testified before the Washington State Senate Committee on Agriculture to express the regret of this administration and the USDA that this tragedy has taken place, and I assured them of our continued cooperation in stopping the outbreak.

Mr. Chairman, I have a short prepared statement that I ask unanimous consent to include as a permanent part of the record, and I will summarize.

Senator DASCHLE. Without objection, your entire statement will be made part of the record.

Secretary ESPY. Thank you, sir. I am planning to meet over the next few days with consumer and industry groups. Yesterday I met with a number of industry groups about this problem and we discussed it in detail. I plan more to meet with others today and next week. I plan to call in certain whistleblowers who serve as meat inspectors in federally inspected slaughterhouses. I want to hear their ideas and their suggestions regarding our course of action for the future. If they have something to say, I want to hear it. I want them to know that they needn't fear reprisals, or be ashamed or upset or concerned about coming to USDA. They serve on the front lines and I am sure they will make some very valuable contributions to us as we struggle with this problem. I assure you that all concerns of the public will be heard by this administration.

Finally, and perhaps most important, it is time that everyone stop trying to blame someone else for this *E. coli* outbreak. We must all share the responsibility for ensuring the safety of food. No one consumer, no one producer, no one meat processor, agency or government official can do it alone. Now is the time for all of us to work together to find solutions to this problem, and to that end I asked Dr. Russell Cross, Administrator of the Food Safety and Inspector Service, to provide me with recommendations for resolving this *E. coli* 0157:H7 outbreak and reducing the likelihood of others.

You will note, Senator Craig, I didn't say preventing other outbreaks. I don't think that that can be done today, but we are moving on a separate track to be sure that it is possible in the future.

The Federal meat and poultry inspection system serves as a primary line of defense for ensuring the safety of food products, but

there are other agencies and other entities inside and outside USDA that also must play a role, including the consumer.

Our strategy includes improvements in education, regulations, testing, enforcement, research, and persuading industry to adopt new technologies. Hopefully, it can be done in a voluntary way. It addresses each step in the farm-to-table continuum where the potential for problems may be reduced. Those steps include raising the animals, slaughtering them, food plant processing, food service processing, and processing at the consumer level. Dr. Cross will provide some of the details on this strategy in his statement today.

Although I have asked that this strategy be developed without regard for the legal, policy and cost limitations, obviously none of those can be ignored before we move forward. But I wanted to be sure, Senator, that creative thinking went into the development of this strategy and that no avenue of resolving this outbreak and future outbreaks would go unexplored.

I particularly must mention the cost limitations that I know will affect these proposals. Some of these ideas are very costly, so we have already begun discussions on their budget impact with OMB and the other relevant appropriations and authorizing committees. Outside experts are also being sought to determine the cost of these scientific strategies.

Another area that I have asked FSIS to address is the recommendations included in various reports prepared by the National Academy of Sciences. Although I haven't had the opportunity to review the NAS reports in detail, the overall theme of their recommendations seems to be that FSIS should move away from organoleptic inspection and design a new prevention-oriented inspection system based on risk analysis. Again, I recognize there are statutory and budgetary barriers to moving full speed ahead to such a system, but rest assured that it is a very high priority with me.

I have been on the job about 15 days, but from everything I have seen, heard and read, it is clear that improvements must be made in the way we inspect meat and poultry in the future. From our investigation so far, we have not found—and I emphasize—we have not found that inspectors failed to do their jobs or that the FSIS inspection program failed. The system functioned as it was designed to function. But the problem is that this functioning, as designed, is no longer adequate; it is no longer good enough.

I agree with the NAS recommendations and the recommendations of many others that a visual inspection program is no longer sufficient to meet the food safety needs of today's consumers. Dr. Cross presented me with a strategy for developing a new model for meat and poultry safety reform. The reform will take place on two tracks and is designed to maximize the performance of current programs while we develop meat and poultry safety programs for the future.

The first track will expand and improve the current inspection system under our present statutes and regulations. For example, I would like FSIS to take advantage of new scientific techniques and technological advances as they become available and are proven effective. But the changes under Track I will be evolutionary rather than revolutionary.

The second track, on the other hand, would be revolutionary—to develop the food safety program of the future from scratch. Everything will be on the table for consideration and I plan to have everyone around the table in order to hear their views.

Mr. Chairman, there are a couple of things that I would like to happen right away. First, we need to talk to OMB and the appropriating committees about getting more meat inspectors right now in these federally inspected slaughterhouses, and also to evaluate the slaughter process.

We know these pathogens cannot be detected upon visual examination, but we need more eyes to see what *can* be seen. There are about 550 vacancies in these slaughterhouses that aren't being filled and, despite the costs, we need to fill the more critical ones. We are going to do that. I will talk to the whistleblowers, as I have said, about their ideas to improve the slaughter process.

We can do more right away to improve the requirement that these federally inspected slaughterhouses keep better records. The good news is that at the Federal slaughterhouse involved, they kept very good records, enabling us at FSIS and USDA to rapidly determine the lot of bad meat, trace it back, retrieve it, and contain it. I would like to see that become a standard throughout the slaughter industry.

The third thing we can do is improve and promote safe handling labels, and improve the instructions for cooking and the handling of raw meat and poultry. Raw meat and poultry contain pathogens; always have, always will. After everything is said and done, if in this particular situation the meat had been properly cooked, we would have had less of a problem. So we need to move right away to developing instructions to promote safe handling and cooking of raw meat and poultry, particularly hamburger.

Certain steps require immediate consideration. One is the voluntary use of organic acid sprays. As carcasses move down the line, they are washed with water, but perhaps we should be washing the outside of them with organic acid sprays and anti-microbial sprays. At least on the outside of the carcass, beyond the visual examination and beyond the washing-down with water, we can reduce the likelihood of *E. coli* contamination.

The second step is to determine whether we can implement rapid tests to isolate *E. coli* 0157:H7. The technology exists: We know of a test coming out of the State of Georgia; we know of a test coming out of the State of Maryland that can isolate this culture within 24 hours.

The question becomes whether or not it is practical to apply this test to meat coming down the line. There are time delays involved, there is expense involved, there is the question of sample sizes involved. Don't hold me to this number, but experts say that if we just take a sample size of 20 percent of all the meat and poultry carcasses coming down the line—just testing a 20-percent sample size is going to cost somewhere around $58 billion. That is an incredible cost. I am not sure that that is accurate. Perhaps we can do a better job of reducing the sample size. I am not sure, but I am sure that I am going to move right away to see if it is reasonable to apply this technology to the situation.

The third thing we can do is to fund research to develop vaccines. We can identify sick or disabled animals and inject them with a vaccine to prevent *E. coli* or other pathogens that exist within them.

The last thing is rather controversial, and it has been mentioned here by two of you: To decide if we should go forward with a petition to the Food and Drug Administration on the approval of irradiation for beef. The USDA has already approved irradiation in poultry and we already use it on vegetables and fruit.

Dr. Cross will talk more about a baseline study for pathogens in raw meat. We have to move to that level to determine the current standard on pathogens in cows and cattle, and he will also talk about the testing of these cows that could be disabled or suspect.

In summary, no meat can ever be 100 percent sterile. We cannot guarantee a zero pathogen level. We also know that if meat were properly cooked up to this 155-degree standard, that would take care of a great deal of this problem.

Visual inspection according to organoleptic standards—diseases you can see or problems on the carcass you can taste or smell—is the standard right now. But that is not good enough. We have to move toward a science-based system. Pathogens exist in raw meat because they exist in warm-blooded animals, but if any child dies as a result of something we have done or haven't done, then it is just not good enough.

So we have been there 15 days. We have tried to assure the public that we are doing everything that can be done to contain this outbreak and to prevent others in the future. We will continue to do that, and with that I thank you for allowing me to testify. I now introduce Dr. Cross, Administrator of FSIS, for any comments he might care to make.

[The prepared statement of Secretary Espy follows:]

PREPARED STATEMENT OF HON. MIKE ESPY, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Mr. Chairman and members of the subcommittee, I very much appreciate this opportunity to appear before you today to discuss solutions to this tragic outbreak of foodborne illness in several Western States. I particularly welcome the willingness of this subcommittee to work in partnership with us to improve the meat and poultry inspection program. I think we all agree that changes must be made.

There are several reasons I wanted to be here today.

First, I want to express the deep sadness all of us in the Clinton administration and USDA feel about the deaths and illnesses that have occurred due to this outbreak of *E. coli* 0157:H7. As a parent and a consumer, I can well understand the fears and anguish this has caused. As the Secretary of Agriculture, I can pledge that I will devote every possible resource to containing the outbreak and working to prevent future ones.

Second, as you all know, I traveled to the State of Washington earlier this week at the request of President Clinton. I had a very productive meeting with Governor Lowry in which I relayed the deep concern of the Clinton administration. I am very encouraged by the excellent cooperation between the Federal, State, and local authorities in dealing with this tragic event. The Governor and I also discussed the steps the State and Federal Government have taken and will take to control this outbreak in the short term. However, we did not discuss what USDA plans to do in the intermediate and long-term future, because I wanted to discuss that here.

I also testified before the Washington State Senate Committee on Agriculture to express the regret of the administration and the U.S. Department of Agriculture that this tragedy has taken place. I assured them of our continued cooperation in stopping the outbreak.

Third, I am planning to meet over the next few days with consumer and industry groups. I want to hear their ideas and suggestions regarding our course of action for the future. I assure you the concerns of all segments of the public will be heard by this administration.

Finally, and perhaps most importantly, I think it is time everyone stopped trying to blame someone else for this *E. coli* 0157:H7 outbreak. We all must share the responsibility for ensuring the safety of food. No one producer, consumer, meat processor, agency, or government official can do it alone. Now is the time for *all* of us to work together to find solutions.

Toward that end, I asked Dr. Russell Cross, the Administrator of the Food Safety and Inspection Service, to provide me with recommendations for resolving this *E. coli* 0157:H7 outbreak and reducing the likelihood of other outbreaks. You'll notice I didn't say *preventing* other outbreaks. I don't think that can be done today, but we are moving on a separate track to be sure it is possible in the future.

The Federal meat and poultry inspection system serves as the primary line of defense for ensuring the safety of food products. But there are other agencies and entities both inside and outside USDA that must also play a role—including the consumer.

The *E. coli* and overall pathogen strategy we have developed includes improvements in education, regulations, testing, enforcement, and research. It addresses each step in the farm-to-table continuum where the potential for problems may be reduced. Those steps include the raising of live animals, during the slaughter process, in the processing plant, during the food service process, and at the consumer level. Dr. Cross will provide some of the details on this strategy in his testimony today.

Although I asked that this strategy be developed without regard for the legal, policy, and cost limitations, obviously none of those can be ignored before we move forward. But I wanted to be sure that creative thinking went into the development of this strategy, and that no avenue to resolving this outbreak and future outbreaks will go unexplored.

I particularly want to mention the cost limitations that I know will affect these new proposals. As you all know, President Clinton is currently working on his economic package. Therefore, I am not in a position to provide you with information on the administration's position on funding for specific proposals and activities. Again, I just want to get the best ideas before us so we can begin discussing them.

Another area that I've asked FSIS to address is the recommendations included in various reports prepared by the National Academy of Sciences (NAS). Although I haven't had the opportunity to review the NAS reports in detail, the overall theme of their recommendations seems to be that FSIS should move away from organoleptic inspection and design a new, prevention-oriented inspection system based on risk analysis. Again, I recognize there are statutory and budgetary barriers to moving full speed ahead to such a system, but rest assured that it is a very high priority with me.

Although I've only been on the job a couple of weeks, from everything I've heard, seen, and read, it is clear to me that improvements must be made in the way we inspect meat and poultry in the future. From our investigation of this *E. coli* outbreak so far, we have not found that inspectors failed to do their jobs, or that the FSIS inspection program failed. The system functioned as it was designed to do.

The problem is that functioning as it was designed to do is no longer adequate. I agree with the NAS recommendations and the recommendations of many others that a visual inspection program is no longer sufficient to meet the food safety needs of today's consumers.

Dr. Cross has presented me with a strategy for developing a new model for meat and poultry safety reform. The reform will take place on two tracks, and is designed to maximize the performance of current programs while we develop meat and poultry safety programs for the future.

The first track is to improve the current inspection system under our present statutes and regulations. That's not to say there won't be any changes; there will be. For example, I want FSIS to take advantage of new scientific techniques and technological advances as they become available and are proven effective. But the changes under track I will be evolutionary rather than revolutionary.

The second track, on the other hand, will be revolutionary. Basically, it is to develop the food safety program of the future from scratch. Everything will be on the table for consideration, and I plan to have everyone around the table in order to hear their views.

Mr. Chairman, I would now like to introduce Dr. Russell Cross, the Administrator of FSIS. Dr. Cross will provide you with more details on USDA's *E. coli* strategy and the two-track inspection improvement plan.

Thank you again for asking me here, and I look forward to working with you in the future.

Senator DASCHLE. Thank you, Secretary Espy. Before calling upon Dr. Cross for his testimony, let me note the presence of Congresswoman Jennifer Dunn from Washington as well. We are pleased she could join us.

We invite you to proceed, Dr. Cross, with your testimony at this time.

STATEMENT OF DR. H. RUSSELL CROSS, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC; ACCOMPANIED BY JILL HOLLINGSWORTH, U.S. DEPARTMENT OF AGRICULTURE

Dr. CROSS. Thank you, Mr. Chairman, and thank you, members of the subcommittee, for the opportunity that you have allowed us to be here this morning to discuss this very serious problem.

I also have more details in my prepared statement, Mr. Chairman, that I would like to provide to the record.

Senator DASCHLE. Without objection.

Dr. CROSS. Thank you, sir. I will briefly paraphrase some of the highlights of that particular testimony. But before I do that, I convey condolences from FSIS to the families and to the friends of those affected by this tragic outbreak in Washington and other States, and I reassure all that we are committed to pursuing every avenue to identify, contain and resolve the cause of this outbreak.

We are also committed to do whatever is necessary to greatly reduce the chances of this ever occurring again. The Food Safety and Inspection Service has been actively involved in investigating the *E. coli* 0157:H7 outbreak since it was reported to us on January 18. We are working closely with the appropriate Federal, State and local authorities to identify the source of the *E. coli* and will continue to do so.

We are sampling product from all identified suppliers to Von's in California, the plant where the meat in question was ground and formed into patties. Our goal is to eventually trace back to where the bacteria originated and determine how it got there. But we agree with the Secretary; that is not enough. We must and we will do more to accelerate the reform of USDA's meat and poultry inspection programs. Current procedures, regulations and statutes are simply not adequate to provide the comprehensive farm-to-table protection that the American consumer deserves.

USDA has recognized that improvements to our meat and poultry inspection program are both feasible and necessary. Since meat inspection began in 1906, we have been evolving. We have made improvements and incorporated those improvements into the existing system without ever changing it. While significant improvements have been made, FSIS is still tied to a system of inspection that is resource-intensive and difficult to change.

When we asked the National Academy of Sciences for their advice, they recommended that we move to a science-based, risk-based inspection system for consumer protection. I couldn't agree

more with those recommendations. We are implementing as many of those recommendations as we can. But that is not good enough. We need to move forward to a strong risk-based system, and for that reason I have recently formed a risk analysis group within the agency committed to cooperate with all Government agencies dealing with food safety as we look at risk analysis, which must contain strong components of risk assessment, strong components of risk communication and, of course, strong components of risk management.

While we have attempted to respond to these recommendations by tinkering with the system, this has not been enough. We have made significant progress through evolutionary approaches, but that approach is not fast enough and we are convinced that we must try, as Secretary Espy mentioned, the revolutionary approach to modernize our system.

I have proposed a new model for meat and poultry safety reform to the Secretary this week. The model will use a two-track approach that will allow us to maximize the performance of our current programs while allowing us to design the meat and poultry inspection programs of the future.

While Track I will be evolutionary, Track II will be, by definition, revolutionary. As we look at Track I under the current program and try to maximize our performance, there are key areas that we must continue to concentrate on.

Public ownership and public input: It is critical in our inspection programs under Track I that we get input from all sources, including our own employees. We must look at the staffing shortages that the Secretary mentioned, not just because of pathogens, but because of other things within our mission. We must look at the structure of the agency, particularly as the Secretary looks at the structure of the Department. We must continue to make labor relations a very high priority for this agency. We have over 7,200 employees in the field. They are important to us. What they think and what they say is important to us.

Under Track I we must enhance our consumer education and service, make science-based decisions, and continue and rapidly expand our ability to reduce pathogens in our meat and poultry supply.

Track II will evolve totally separately from the current system. We will seek input from all sources and not be hampered in our thinking by tradition, current statutes, or even current resources. We want to give something to Secretary Espy that is truly the food safety system of the future. Track II will almost certainly be developed in an open, broadly based participatory process that strongly relies on TQM principles.

Let me now discuss with you the tragic events that brought us here today involving *E. coli* 0157:H7. USDA is committed to work with other Federal, State and local authorities, and industry, to reduce the likelihood of future outbreaks of this or any other pathogen found in the food supply. Science has not eliminated all risk associated with bacteria in foods.

We must take dramatic steps to reduce this risk. The multiple-step strategy that I have proposed to the Secretary includes education, regulation, testing, enforcement, risk analysis, and research

that is targeted to address each step in the process where potential problems exist. This strategy was also supported by the Secretary's National Advisory Committee on Microbiological Criteria for Food at their recent meeting in Florida this week.

USDA intends to address all pathogens in meat and poultry as it implements this strategy. Agencies throughout the Department of Agriculture and other Departments must work closely together to focus their efforts to address each step of these intervention systems. Our strategy will address critical control points throughout the production, processing and distribution cycle. These different cycle locations include the live animal, the slaughter process, the processing plant, food service, retail establishments, and communicating with the public and the consumer.

Here are a few strategies under each of those categories. Under live animal—and these appear in more detail in my prepared statement—we need more research to determine the source of *E. coli* 0157:H7 and other pathogens. We need the information derived from this research to develop control and intervention strategies.

We need to accelerate our look for rapid tests to identify carriers of pathogens on the farm before they enter the slaughter plant so that we can design our inspection system differently around those cattle that we know are positive for pathogens.

We need to develop methods for the identification and trace-back of animals from the slaughter plant to the farm. We need to develop on-farm pathogen intervention programs which would include vaccines, management, or any other approach that we identify through our research that will reduce or eliminate pathogens in these warm-blooded animals.

The slaughter plant is a very important control point for pathogens. We will recommend to the Secretary that we expand the national microbiological baseline study which has been conducted since last October in all the steer and heifer slaughter plants in this country to include cows, calves, poultry and swine. We intend to include all these different classes of livestock in the national microbiological monitoring survey before the end of this year. It is also our intent to monitor at least six, and perhaps more, of the key pathogens, including 0157:H7.

We will recommend rapid implementation of HACCP-based food safety systems, going from the farm all the way through slaughter and processing. We will accelerate the development of new technologies, such as the organic acid sprays or any other intervention system that will effectively reduce these pathogens.

If our microbiological baseline surveys indicate that the pathogen levels aren't being reduced, then we will move very quickly to mandate these intervention strategies if they are not being voluntarily used by the industry. We will also begin microbiological testing of key pathogens in disabled or suspect animals to learn more about the etiology of these particular organisms as we go back to the farm. We will mandate enhanced record-keeping for trace-back from slaughter to the farm.

The next area is the processing plant. We will establish through rulemaking, and enforce, time and temperature requirements for handling meat and meat products as they affect pathogen growth. We will finalize in the next few weeks cooked patty regulations for

patties cooked, pre-cooked and fully cooked in Federal establishments.

As the Secretary mentioned, we will mandate safe handling and cooking labels for all raw meat and poultry products destined for food service and retail. We will accelerate the research necessary to obtain FDA approval for irradiation of beef. We will mandate record-keeping and trace-back from processing back to the slaughter plant.

Moving to food service and retail, education and training for all food handlers is absolutely necessary, but it is not going to be accomplished by one governmental agency, perhaps not even by one department. It must be a nationwide effort involving State governments, Extension Service and the industry to educate the food handlers at food services and retailers. You will hear from Dr. Archer about Healthy People 2000. This is an excellent program that allows us to have targets for the reduction of pathogens in the food supply.

The last category is consumer awareness and education. We must work with key Federal and State agencies and industry to initiate a national awareness campaign for the public. Of course, safe handling labeling instructions is going to be part of that campaign, but we have tremendous capabilities in this country with our information multipliers in Federal, State and private industry organizations to deliver this information once it is developed.

I will recommend to the Secretary that he appoint an *E. coli* 0157:H7 interagency, interdepartmental food safety council to coordinate all research, regulation and outreach activities as we try to deal with this and other pathogens.

In summary, Mr. Chairman, I feel that the comprehensive strategy that we have outlined here today for addressing 0157 and other pathogens will maximize the performance of the system. It is consistent with Track I of the model of reform that we are proposing. It will establish a basis for pathogen reduction using the Hazard Analysis Critical Control Point (HACCP) system, and risk analysis principles that will eventually become the cornerstones of Track II.

Mr. Chairman, thank you again for giving me the opportunity to talk to this subcommittee today. We in FSIS take our job of protecting consumers very seriously. I am very proud of the efforts of FSIS employees to make the meat and poultry supply safe for the public, but there is no question that the safety of these products can be improved. I believe that the approaches that I have provided to the Secretary for his consideration will help us develop a new generation of food safety programs and I look forward to working with you and this subcommittee in accomplishing these goals.

In closing, food safety is everybody's business. It is the regulator's business, it is the industry's business, it is the consumer's business. By working together, we can make this happen.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Cross follows:]

PREPARED STATEMENT OF DR. H. RUSSELL CROSS, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Mr. Chairman and members of the subcommittee, I am pleased to have this opportunity to appear before you today. I am Dr. Russell Cross, Administrator of the

U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). With me is my assistant, Dr. Jill Hollingsworth.

On behalf of all the employees of FSIS, I would like to convey our condolences to the families and friends affected by the *E. coli* outbreak in Washington and other States. We are all committed to pursuing every avenue to identify, contain and resolve this outbreak.

FSIS has been actively involved in investigating the *E. coli* 0157:H7 outbreak since it was reported to us on January 18. Although we may never be able to identify the source of the *E. coli* 0157:H7, we are working closely with the appropriate Federal, State, and local authorities on this investigation and will continue to do so.

Knowledge about *E. coli* 0157:H7 is relatively limited at this point. We do know that the group of bacteria called *Escherichia coli* are normally found in the intestines of warm-blooded animals such as cows or humans. It can be found in contaminated water, and raw milk. It is not known at what level or dose the pathogen becomes hazardous.

In 1982, a rare and more virulent strain, called *E. coli* 0157:H7, was identified as the cause of two outbreaks of human illness. Since that time, there have been other reported outbreaks. Sources of *E. coli* 0157:H7 have included raw meat, water, unpasteurized milk, and low-acid apple cider.

Research has shown that freezing at −80 degrees Celsius and storage at −20 degrees Celsius for up to nine months will not significantly reduce the population levels of *E. coli* 0157:H7. If the pathogen is present, it can multiply very slowly at temperatures as low as 44 degrees Fahrenheit.

Surveys reported in scientific literature or conducted by FSIS suggest that *E. coli* 0157:H7 is found infrequently in meat in the United States. FSIS surveys indicate that calves are more likely than other bovines to harbor this organism. However, even in calves, the prevalence is very low.

FSIS surveyed brisket and ground beef for *E. coli* 0157:H7 during the period 1987–1990. Of the 1,668 samples taken, only 2 were positive. FSIS has not recovered the organism from poultry in any of its surveys.

E. coli 0157:H7 does not cause illness in animals. It can be carried in the intestinal tract of an animal, although it can also be found on the animal from contact with feces, and in raw milk. Animals carrying this bacteria appear normal at the time of FSIS inspection, which is performed for each and every animal and carcass. We do not know if the bacteria can be found elsewhere, such as circulating in the blood or lymphatic system. We do know, however, that it can be transferred to the meat of a carcass from feces or milk.

As you all know, we have an inspection program now that is organoleptic. That means we inspect visually, and by touch and smell. We require meat to be trimmed of visible contamination from feces or milk, but bacterial contamination generally can't be observed through organoleptic inspection.

Right now, there is no rapid test available that can be performed on raw meat and poultry to adequately detect the presence of microbiological pathogens. We'd like to have one, but that type of test standing alone won't solve this food safety problem. A microbiological control and prevention program must cover all steps from the farm to the table.

At the present time, meat and poultry inspection laws do not define raw meat or poultry containing bacteria as adulterated. The Court of Appeals for the District of Columbia has held that the presence of bacteria in raw meat and poultry does not constitute adulteration because bacteria are inherent in raw meat and poultry. The Court also concluded that Congress did not intend inspections to include "microscopic examinations." [American Public Health Association v. Butz, 511 F.2d 331 (D.C. Cir. 1974)].

Even with the limitations of science and our statutes, there are things that we can do now to reduce the likelihood of future outbreaks of the illness caused by *E. coli* 0157:H7 and other pathogenic bacteria. As Secretary Espy stated, many scientific experts and the National Academy of Sciences have long recommended that FSIS ultimately move away from organoleptic inspection and design a new, prevention-oriented inspection system based on risk analysis.

Therefore, I am today announcing that FSIS has developed a New Model for Meat and Poultry Safety Reform. This model will be a two track approach that allows us to maximize the performance of current programs while redesigning meat and poultry safety programs for the future. While Track I is evolutionary, Track II will be revolutionary.

A TWO TRACK APPROACH TO REFORM

USDA has long recognized that improvements to meat and poultry inspection are both feasible and desirable. In the past year, the agency has implemented several improvements that have the potential to make a good system better. For example, the agency launched the first national microbiological baseline data collection program of meat and poultry. By establishing the current microbiological status of the products it inspects, FSIS will be able to set realistic targets for the reduction of potentially harmful pathogens.

FSIS has also made strides in approving new technologies that employ sophisticated scientific techniques, such as permitting the use of antimicrobial sprays on beef, pork, and other meat carcasses, as well as allowing the use of Trisodium Phosphate (TSP) and irradiation in poultry processing. And, perhaps most importantly, FSIS has opened new lines of communications with its employees and constituencies as it has started to develop a comprehensive strategic plan that will guide its operations in the 21st century.

While improvements have been made, FSIS is tied by law to a system of inspection that is resource intensive and difficult to change. Recommendations received from the National Academy of Sciences and others urge that FSIS move to a science-based, risk-based system. However, it has proven to be virtually impossible to evolve the current system into the system of the future while carrying the daily routine of organoleptic inspection. Instead, it has become necessary to consider taking the bold step of developing the inspection system of the future, from scratch, while still maintaining the current system until the time when the agency can make a total shift from one to the other.

This approach will be referred to as the **two track approach.** Track I involves the implementation of six major initiatives for maximizing the performance of the current inspection system. Track II represents the agency's commitment to design, test, and implement the kind of food safety program that will serve the needs of American consumers for the new century.

Maximizing the Performance Of The Current Inspection System—Track I

The agency's short-term program for maximizing the performance of the current inspection system is comprised of six major initiatives that provide for the best utilization of resources under existing law. The following points make up Track I.

Public Ownership—FSIS will actively involve all of its constituencies in an open, participatory decisionmaking process.

A key to the agency's future success will be to seek input—to ask and to listen and not work from behind closed doors. FSIS is responsible to the public, and public ownership means actively involving all constituencies, including consumers, industry, scientists, other Federal, State and local agencies responsible for regulating food safety, and the agency's work force, in an open, participatory decisionmaking process.

Staff and Structure the Agency—FSIS will maximize the current program based on today's needs.

FSIS will maximize the current program to ensure that existing staff and structure are aligned to be optimally utilized. At present, the agency is reviewing priorities and making staff changes accordingly.

Labor Relations—FSIS will build a strong, mutually supportive relationship with its employee organizations.

FSIS will build a strong and mutually supportive relationship with employee organizations by placing more employees on task forces so that major initiatives will not come as a major surprise. Employees who are on-the-line and inplant have valuable practical knowledge of how regulations work or don't work, and they will get a chance to comment on proposed regulations and other changes to inspection.

Reduction of Pathogens—FSIS will determine the microbiological status of raw meat and poultry and establish goals for reducing pathogens.

FSIS has already begun a nationwide study to determine the microbiological baseline of the nation's meat and poultry supply. Data will be used to support specialized studies of meat and poultry. The data will help determine how future prevention and inspection systems can reduce microbiological contamination.

A major feature of the goal to reduce pathogens will be through industry use of new technologies, such as the use of irradiation, of Trisodium Phosphate in poultry processing operations, and of organic acid sprays on cattle and swine. This will be discussed in more detail later in my testimony.

Consumer Service and Education—FSIS will strive to raise consumer awareness of safe food practices for meat and poultry products.

The agency's food safety education program began two decades ago and has involved many different kinds of activities—too many to describe fully today. Millions of copies of our food safety publications have been distributed. Our videotape for food handlers has been widely used in international and retail food service training programs. Our toll free Meat and Poultry Hotline for consumers, which received about 138,000 calls last year, provides instant answers to questions about food safety.

However, as evidenced by the *E. coli* outbreak and the thousands of other cases of foodborne illness that occur each year, many people are not aware of safe food-handling practices. FSIS now plans to intensify its educational efforts. We will work cooperatively with other Federal and State government agencies and with the private sector to get out the food safety message.

Science and Technology—FSIS will improve or enhance the current inspection system using risk analysis, new scientific techniques, and technological advances.

Science will be the centerpiece of much of the Track I program. FSIS will make decisions based on science when data are available and will strive to develop data when they are not available.

FSIS will use risk analysis, which includes risk assessment, management, and communication. With help from the advisory committees and others, FSIS will develop quantitative risk analysis models that will allow it to identify risks and provide the rationale for policy and resource allocation.

Detection capability is another area where scientific advances play a large role. Huge strides have been made already. Rapid analytical tests have been developed to screen samples for residues of antibiotics and sulfa drugs. More tests like these—not just for chemicals, but also for bacteria—are needed.

Through scientific research, FSIS will improve its understanding of the sources and modes of transmission of pathogens to develop and implement effective control measures. Research will also be directed at learning more about the resistance of pathogens to heat, freezing, pH extremes, water activity, and other factors that affect food safety.

The Regulatory Program for the Future—Track II

FSIS will move forward aggressively to design a regulatory program for the future that is the best possible system for protecting consumers. The agency will consider different options for the *process* to be used to develop Track II. As a first step, the agency will convene a small task force from within the agency to work with outside stakeholders such as Congress, professionals from the public health sector, consumer groups, industry, other Federal agencies, and others in order to determine the attributes of a regulatory model of the future. FSIS has proposed a Meat and Poultry Safety Summit as one way of bringing together all of the parties interested in food safety to get input for both the process and the content of Track II.

Track II will be developed in an open, broadly-based, participatory process, following the process improvement and employee involvement tenets of Total Quality. The Track II development cycle will define the requirements of a Meat and Poultry Regulatory Program for the future, thoroughly test the proposed reforms and provide outreach and public involvement activities to assure all constituencies understand what is being proposed and have had ample opportunity to participate. In the interim, USDA will continue to maximize the performance of meat and poultry safety programs following a series of measures as described in the following strategy.

STRATEGY TO ADDRESS PUBLIC HEALTH PROTECTION RELATED TO E. COLI 0157:H7 AND OTHER PATHOGENS (TRACK I & II)

USDA will take the lead, acting with other Federal, State and local authorities, to reduce the likelihood of future outbreaks involving *E. coli* 0157:H7 in beef. This strategy will be in Track I and Track II.

Experience and research have shown that *E. coli* 0157:H7 and other potentially deadly pathogens remain a part of the food supply. The state of scientific knowledge is simply inadequate to predict the next outbreak of foodborne disease or to eliminate all risks of bacteria in foods. However, steps can be taken to reduce the pathogen levels in meat and poultry, and to enhance consumer understanding of the safe handling of meat and poultry products, with resulting reductions in the likelihood of illness.

This strategy includes education, regulations, testing, enforcement, risk analysis and research targeted to address each step in the process where the potential for problems may be reduced. Some specific steps focus on *E. coli* 0157:H7 in beef. How-

ever, USDA intends to address all pathogens in meat and poultry as it implements the strategy.

Statutory change may be needed. Agencies throughout USDA, including the Food Safety and Inspection Service, the Animal and Plant Health Inspection Service, the Agriculture Research Service, Extension Service and other research and education components, will work closely with the Department of Health and Human Services to concentrate efforts to address each step.

Critical control points for reducing the likelihood of future outbreaks will be identified throughout the production/processing cycle.

- **The live animal**—particularly calves and mature cattle, which appear to be the most likely "carriers" of *E. coli* 0157:H7
- **The slaughter process**—where pathogens from the live animals can be transmitted to the meat and trimmings used for hamburger patties
- **The processing plant**—where pathogens may proliferate and key cooking and labeling steps occur
- **The food service process**—to promote proper handling and adequate cooking
- **Consumer education**—to discourage consumption of undercooked hamburgers and encourage food safety practices in the home.

In addition, the strategy includes measures to strengthen staffing, training, and technological support for the Federal meat inspection system and to provide for prompt review of scientific findings through a coordinated interagency *E. coli* 0157:H7 task force.

Initially, the primary focus will be on *E. coli* 0157:H7 in beef. However, USDA will recognize opportunities to expand the scope of these actions and reduce risks of other pathogenic bacteria in the meat and poultry supply.

As Secretary Espy pointed out in his testimony, cost limitations will affect these new proposals. The President's budget is currently being developed, so I cannot provide you with information on the administration's specific funding proposals. But I would like to lay out our plans of future activities to improve food safety programs.

Live Animal Activities

- **Conduct comprehensive research**—Determine the source and incidence of *E. coli* 0157:H7 and other pathogens. Conduct epidemiological field studies for risk analysis, control, and intervention strategies. Collect baseline data on pathogen presence and monitor for trends, geographic differences and causal links.
- **Conduct on-farm investigations**—Immediately conduct targeted on-farm investigations to confirm current assumptions about sources and good preventive measures that can be quickly implemented.
- **Develop rapid methods**—Develop rapid tests and other methods necessary to identify pathogens at the critical points.
- **Establish methods for the identification and traceback of animals**—to facilitate on-farm prevention programs and permit better investigation of the source of *E. coli* 0157:H7.
- **Develop on-farm pathogen prevention program**—Support research for pathogen prevention, including development of vaccines. Integrate and analyze data on pathogens from State, universities, veterinary diagnostic laboratories, and FSIS data base. Work with producers to introduce voluntary, industry-supported herd certification program.

Slaughter Plant Activities

- **Expand microbiological baseline program**—Immediately add cows to national microbiological baseline monitoring (now limited to steers and heifers). Also expand to poultry and swine. Encourage plants to collect microbiological data. Use data to establish targets for reducing pathogens.
- **Evaluate current slaughter and processing methods**—Assure they are adequate to reduce carcass contamination and prevent temperature abuse and other potential causes of bacteria proliferation. Reinforce mandatory trimming of all fecal and milk contamination in slaughter operations. Implement a stronger pre-operational sanitation inspection program in meat slaughter plants.
- **Use organic acid and other prevention systems**—Encourage use of organic acid sprays or other prevention systems to reduce pathogens on surfaces of beef carcasses. If voluntary use is inadequate, mandate use.
- **Test "disabled" and other "suspect" animals**—Test "disabled" and other "suspect" animals to determine if *E. coli* 0157:H7 is more prevalent in "sick" animals.

- **Enhance veterinary coverage of higher risk slaughter plants**—Evaluate veterinary staffing in higher risk slaughter plants to ensure that public health expertise is proportional to the risk.
- **Mandate records**—Issue regulations to strengthen requirements that slaughter plants maintain complete and accurate records of all their transactions (purchases and sales). Focus on records that facilitate traceback and control measures.

Processing Plant Step Activities

- **Control bacteria in trimmings**—Establish and enforce strict time and temperature requirements to reduce bacteria proliferation in meat trimmings. Include steps to monitor storage and transportation. Restrict use of incoming products that exceed established temperatures.
- **Finalize "patties" regulation**—Issue the final regulation for cooking and handling of patties produced at establishments. Pending the effective date of the final rule, issue instructions to field inspectors to encourage voluntary compliance and report any significant deviations immediately. Also issue regulations for other ready-to-eat beef products.
- **Mandate safe handling labels**—Mandate safe handling instructions for labels on all raw meat and poultry products. Issue instructions to the field on approval of safe handling statements for voluntary industry use, pending mandatory rules.
- **Research irradiation**—Give immediate priority to research to support a petition for FDA approval of irradiation for fresh ground beef and beef trimmings.
- **Evaluate inspection in processing plants**—Use potential public health risk to make staffing and inspection task adjustments in processing plants.
- **Recordkeeping requirements**—Assure that processing plants maintain complete and accurate records of all their transactions (purchases, formulations, and sales). Focus on records that aid in identification and traceback.

Food Service Step Activities

- **Sponsor teleconference**—Invite the Department of Health and Human Services to join with USDA in sponsoring a teleconference for State and local public health authorities to share information on such subjects as food safety requirements and their enforcement.
- **Help State enforcement programs**—Using the teleconference as the first step, actively lead a major initiative to cooperate with States to provide emergency and ongoing Federal assistance and advice. Stress the need for better enforcement of safety standards in retail stores and restaurants.
- **Educate food handlers**—Use the targeted education program for food service employees, day care centers, nursing homes and similar institutions to stress proper cooking and handling.
- **Educate fast food restaurant employees**—Call upon corporate leaders of fast food "chains" and other restaurants to educate their food service employees and follow up to ensure that information is understood and applied correctly.
- **Label school lunch products**—Require "safe handling" inserts and prominent cooking labels on all school lunch products. Send notices to School Food Service Directors to alert them to concerns about thorough cooking. Consider a similar campaign for other Federal facilities (military, Veterans hospitals, etc.)
- **Enhance model codes**—Work with FDA and the States to assure adequate controls in the model retail code.

Consumer Awareness Step Activities

- **Enhance consumer awareness campaign**—Develop a national consumer awareness campaign to stress improved public understanding of the risks of unsafe food handling practices. Prepare specialized materials for the campaign, such as columns for small newspapers, information for magazine articles, video news releases and media packages.
- **Promote materials**—Promote existing and new consumer education materials. Work with "information multipliers," such as State Extension agents, industry groups, academic institutions and consumer and health groups to maximize distribution.
- **Promote the USDA Hotline**—Expand public awareness of USDA's toll free Meat and Poultry Hotline as a resource for consumers with questions about safe handling practices.
- **Expand food safety education**—Increase cooperative efforts with other agencies and organizations who share roles as food safety educators.

Federal Government Process

- **Improve inspection**—USDA will improve its meat inspection program to respond to the known microbial risks to the public health. Food inspectors and veterinarians will be trained and provided with the technology, such as diagnostic tools and information systems, needed for modern inspection.
- **E. coli Task Force**—An interagency task force will be formed to address other needs—research, regulatory, etc.—that will aid in future prevention activities.

The comprehensive strategy for addressing *E. coli* 0157:H7 and other pathogens will maximize the performance of the current meat and poultry safety programs as envisioned for Track I of the model for reform. It will also establish a solid basis for pathogen reduction that will be the cornerstone of Track II—the inspection model for the future.

Mr. Chairman, thank you again for giving me this opportunity to appear before you today. We in FSIS take our job of protecting consumers seriously—from the inspector on the front line to senior management officials. We have the safest food supply in the world, and we believe these reforms will help us develop an even safer, new generation of food safety programs. I look forward to working with all of you as these programs advance.

Secretary ESPY. Mr. Chairman, before we take questions, just three brief comments. First—Government bureaucracy—when you hear that, you tend to think that it is synonymous with delay and hesitation, and I hope that by our testimony you now see that we are improving the response and the response time by the USDA to a myriad of problems.

Second, the Microbiological Advisory Committee met in Orlando, Florida on Tuesday, the same day I was in Olympia, Washington. They were to consider business in other areas, and the agenda was of a different type, but we asked them to consider this *E. coli* issue. Yesterday I received a report with their suggestions for microbiological testing standards, but I haven't had time to review it.

Third, this is Dr. Jill Hollingsworth, an assistant to Dr. Cross. She is the first person who briefed me on this on my second day in the office. She is dedicated, proficient, and she has been the point person in FSIS on this *E. coli* outbreak. So I asked her to come to help answer any questions that you might have.

Senator DASCHLE. Thank you, Secretary Espy, for those additional comments, and you, Dr. Cross, for your comprehensive statement about the approaches being considered by the Department.

Secretary Espy, your first comment relating to the bureaucracy leads me to my first question. You mentioned the two-track system, one being evolutionary, the second being revolutionary. I am still trying to get a better grasp of when this will happen. Can you clarify when the two tracks will be implemented?

Secretary ESPY. Perhaps the others on the panel can help me. Regarding more meat inspectors, I hope it can be done fairly soon. It has some budget impact, of course. There are 550 vacancies within the federally inspected slaughterhouses—550 vacancies.

Senator DASCHLE. Out of how many? What is the total number? Do you know?

Dr. CROSS. 7,200.

Senator DASCHLE. 7,200?

Secretary ESPY. 7,200. They have got to be paid and we have got to find some money. We have to go to OMB to talk about it and then we have to come to these appropriating committees. There are other issues with regard to union concerns that we have to address as well, but I hope that, working with you and working with the

OMB, we could do this fairly soon. Again, these pathogens cannot be detected by visual examination, but there are many other things that get through the system that *can* be seen and *should* be seen.

Second, I would think that the safe handling labels and cooking instructions, including the instructions on cooking patties—can be done fairly soon. I am asking for help here, but I don't think that we have a time problem with that.

Dr. CROSS. Let me comment, if I could, Mr. Secretary. Mr. Chairman, most of the strategies that I outlined this morning I would consider to be in Track I, and we will put those on as fast a track in Track I as possible, given constraints of resources or what not.

Track II I visualize more as a think-tank, blue-sky approach that could take two to three years, but we can't wait two to three years to address the pathogen issue. So that is our highest priority and that is why it is in Track I. So almost everything that I outlined this morning and have proposed to the Secretary is in Track I.

Secretary ESPY. I promise you to be a Secretary that will work against fuzzy answers, honestly, and I am not saying you gave one. [Laughter.]

The CHAIRMAN. However——

Secretary ESPY. However, honestly, because I respect these 2 individuals—I have worked with them very closely over the last 10 days. They are dedicated, professional Government employees. The safe handling labels will be done very quickly. The enforcement of the slaughterhouse record-keeping—we have a very good standard right now, but some of these slaughterhouses don't meet the current standard. The enforcement up to standard would be immediate. Where we can improve that to make for an even better standard of record-keeping, that will be done immediately. Hiring more inspectors must be done in consultation with OMB because the President has to sign off on that and then we have to come to you to ask for the money. The organic acid sprays—I would hope that just by sitting down with consumer groups and industry groups, a lot of this can be done on a voluntary basis. I hope to achieve that. We already started yesterday with industry groups who arrived in my office on three hours' notice to listen to what we had to say, and it was a good meeting. They agreed with a lot of things we had to say. We must finish that dialog before we can proceed. There may be EPA concerns. There may be other concerns I am unaware of, but we will address those as soon as possible.

The research to isolate this culture exists. We have studies from the University of Maryland and the University of Georgia available to us. The question becomes the sample size, the expense of it, and whether you would cause undue delay between the application of the sample and the delay in the processing of the meat, both processed and raw. It will take some time to address that issue.

The vaccine research is ongoing. I want to move more expeditiously on the irradiation process so we can petition FDA for its approval. It is already approved for poultry and is being used on fruits and vegetables and spices.

There could be EPA concerns there as well, and consumer concerns. We have to educate them that a low dose of radiation in this regard is going to be OK. It is going to take a lot of convincing, but that will start very soon.

Senator DASCHLE. Chairman Leahy has a conflict in his schedule that will require his absence this morning, and I appreciate very much this opportunity to spend the time that he has and I would ask him for any comments before he departs.

The CHAIRMAN. Mr. Chairman, I discussed this issue with you and I know that we have heard from other Senators on this issue, representing all parts of the country. I commend you for holding this hearing. It is a service for all our colleagues in the Senate.

Mr. Secretary, I again appreciate the briefing you gave me earlier and thank you for keeping about this and that you have kept us apprised each step of the way. I agree with you on how good it is that the experts within your own Department and people outside, non-governmental people, have pulled together to work with you. I cannot overstate the importance of Senator Daschle holding this hearing and you taking so much of your time to work with us. It is going to be helpful to everybody.

Mr. Chairman, I compliment you and Senator Craig and all the others who have worked so hard on this hearing.

Senator DASCHLE. Thank you, Chairman Leahy.

The CHAIRMAN. Thank you, Mr. Secretary.

Secretary ESPY. Thank you, sir. Mr. Chairman, Dr. Hollingsworth tells me that 14 of the strategies we have outlined today could be implemented in less than 12 months. You might want her to elaborate on that if she cares to.

Senator DASCHLE. Please.

Dr. HOLLINGSWORTH. Of the strategies that Dr. Cross just outlined, there are 33 specific strategies and he has asked the staff to come up with a proposed time line for implementation of each of those 33 strategies. Some of them, of course, have no ending time because they are research efforts and don't have a start and end point. But of the 33 that are strategies for starting and implementing, 14 of those can be accomplished within 12 months or less, some of them as quickly as 2 months.

Senator DASCHLE. And can you give us any indication as to the remaining strategies with regard to time frame? I understand completely how you necessarily have to be—to use the word "fuzzy"—but I would also appreciate your expectations with regard to time frame, and if you can enlighten us to whatever extent possible, I think it would be very helpful to this subcommittee.

Dr. HOLLINGSWORTH. Of the strategies that Dr. Cross mentioned that don't have an end, such as research, we are looking at a two-year total package for implementing all of them. Fourteen of them, or more than half, can be implemented within 12 months. That is our proposed time line.

Senator DASCHLE. I am sure that you have all been concerned about unnecessarily reinventing the wheel, so to speak; that you have had the opportunity to examine inspection systems in other countries, especially Dr. Cross. Can we learn from the experiences in other countries and adapt those experiences to our own situation?

Dr. CROSS. Mr. Chairman, we don't live in a vacuum so we have to look at the rest of the world and see if there is a better mouse trap, and we have been doing that for at least the last year. Just this year we formed a Quadrilateral Commission with Canada,

New Zealand and Australia, and we meet at least twice a year to compare our systems of inspection to see who has a better mouse trap.

It is odd that this particular quadrilateral group is moving down a very similar path, but we are learning a great deal about one another. This fall, FSIS will sponsor a worldwide safety conference in which we will bring the top 3 meat safety people from about 20 different governments throughout the world to share what we know.

This is what we are going to be doing a lot in Track II. We know our system is not the only system. We can always find better ways to do it. Hopefully, we will come up with a lot of those better ways ourselves, but we are not going to be ashamed to use some better system if it exists.

Senator DASCHLE. Thank you, Dr. Cross. I have a number of other questions, but let me turn to my colleague, Senator Craig, for questions that he may have.

Senator CRAIG. Mr. Secretary and Dr. Cross, thank you for your detailed testimony. It is greatly appreciated by all of us, and your method of approaching it is also appreciated—the rapidness, the willingness to move, but also the recognition that it is a fairly sizable task at hand and that there is a lot to be done.

One of the things we have found interesting—and sometimes we are quick to criticize what may not have been done in the past that should have been done—relates to a statistic that we received from you folks about illnesses that result from food, foodborne illnesses. Ninety-five percent of foodborne illnesses are a result of biological agents.

Yet, if I think back over the last 10 years, this Congress, and therefore the attention of the public, has been focused on food safety as it related to chemicals, if you will, or what chemicals might get into the food chain or into the food process. That makes up only 1.5 percent of food illnesses. It is very possible that we have mis-focused a little bit, or at least maybe our intensity should have been a little wider-spread.

My question, Dr. Cross, concerns the 550 vacancies in inspection. Can you fill them? Are there 550 qualified people out there to fill them relatively immediately, if you have the money, Mr. Secretary, to do so? What type of person are you looking for, i.e., their qualifications?

Dr. CROSS. Let me first address the 95 versus 1.5. I couldn't agree more. Ten years ago, we had a significant problem with violations of chemical residues in the meat and poultry supply and we have had an excellent program in FSIS to address that, in cooperation with strong preventive programs in industry. We have probably had a 10- to 30-fold decrease in the violations to the point where we are almost approaching zero.

So I knew months ago that it is time to refocus on pathogens. It is time to refocus our attention and resources precisely because of that 95-percent figure. So you are right on target.

Senator CRAIG. When we talk about the available resources necessary, Mr. Secretary, I don't think any of us believe that you are going to lessen your concern about chemical contamination and that type of thing. But is it possible to shift some interagency resources, if you will, for that purpose?

Dr. CROSS. We have felt all along that we have had a strong, successful program on monitoring chemical residues, and that should continue. We always have to monitor for chemical residues in the meat and poultry supply, so there are not going to be great opportunities to shift from that resource base. But we also monitor economic adulteration—whether it has the right amount of protein or fat content. Some of those resources could be shifted to microbiology.

I have publicly stated, Senator, that this agency is responsible for public health protection. It is also responsible for economic adulteration and labeling, and we probably spend half of our resources on the other side of that fence. It probably should be greatly weighted on the public health side as we look down the road—maybe 70 percent for public health and 30 percent for economic adulteration. But that is something we have got to think through, and my thoughts and the thoughts of my key staff have already shifted to public health protection.We cannot fill 500 vacancies tomorrow. If we have the resources, we can probably fill as many as 160 or 170 and train those people before the end of this fiscal year. We do have a national training center for meat inspectors that has a very good training program with dozens of different training courses dealing with chemistry and microbiology, etc., and that program has been ongoing for the last six years. So if we had the money right now to hire 500, we couldn't do it, but we could certainly do it over the next 12 to 15 months.

Senator CRAIG. In the makeup of that 500, are you going to be looking for professionals to enable us to do some chemical analysis and microbiological monitoring—things we are now beginning to talk about? My experience or knowledge of meat inspection and inspectors doesn't take us into that realm at all because of the visual nature of the current——

Dr. CROSS. Senator, we are going to do both. Even though we say we are going to move away from an organoleptic inspection system, we still have to maintain certain procedures during slaughter and processing. We have to look for indications of disease, we have to look for physical contamination, and we have to have those inspectors present to do that.

On the processing side, we are considering a move toward the employment of food technologists, using upward mobility and training of our current work force, if necessary, to move them into upward positions. The Office of Personnel Management is auditing the food technology series to define the role and characteristics and the job duties of that particular series.

Unquestionably we need to be move in this direction and the kinds of people we hire will have to be able to monitor microbiological data, chemical data. That is critical to our future.

Senator CRAIG. Mr. Secretary, this is a double question, for you and Dr. Cross. We all recognize by our comments, and by your testimony, that what we are looking at here, as it relates to the meat supply system, is a three-component system—production, slaughter and processing, and post-processing food handling as three distinctively different components.

I know that FSIS primarily focuses, by law and by nature, on the second component. Yet, you have spoken to the first and you have

spoken to the third. In the two-track approach as it relates to where USDA may be going, how do you plan to address the three parts instead of the single part? You do recognize the importance of all three.

Both of you concluded by recognizing the phenomenal importance of the third; that everything can be healthy and safe right up to the grill or the skillet in the home and if that fails, all might fail.

Dr. CROSS. Cooking is a critical control point. It is a very important critical control point.

Senator CRAIG. But you have no authority over that right now.

Dr. CROSS. We allow the States and the local authorities to exercise that authority, but we think there ought to be many critical control points. We are not saying that we should ever diminish the importance of cooking as a critical control point, but we are now saying that we need a farm-to-table food inspection system that has critical points beginning on the farm and going all the way to the table.

Senator CRAIG. A farm-to-table approach would be a massive undertaking for USDA. We are already talking about lots of money. I believe the Secretary spoke of $50-plus billion. How would you plan, or have you thought about how you would plan, to incorporate and relate to State and local inspections or inspection authorities?

Dr. CROSS. In regard to the cost and who is responsible for what, when we use the HACCP approach, Senator, that responsibility is not only going to rest with the Federal Government; it is going to rest with industry and, of course, some State authorities. We must have a much better integrated system for all these parties so we can share the responsibility and we can share the cost.

On the farm, it is logically going to begin with the industry, but I think the Federal system ought to move toward the farm also, whether it be FSIS or APHIS or other governmental agencies using their authority for trace-back and prevention on the farm. You are going to find a very willing industry to put these processes in place. In some cases they already are in place. We have seen it with other things that the industry has done in the chemical area.

If we can get the battle cry on pathogens, you are going to find a lot of players coming to the table wanting to get into the game because they all know that if food safety is not paramount, then there won't be a business.

Secretary ESPY. Senator, I will start where Dr. Cross finished. We have already done some things at USDA that I have been advised by our general counsel that we are on thin ice about, and I say this only because it is a community effort and we may have to go beyond our current authorities.

For instance, we recalled, retrieved, and are detaining this so-called tainted meat, but we are doing it on the basis that it has harmful pathogens. We only have authority under the meat and poultry inspection acts to detain meat considered to be adulterated, not pathogenic. So we have already done some things that might be outside the scope of our authority, but we have done it anyway because I think that it is consistent with our mission—to protect the food supply. So when it comes to these other things, we are going

to have to come and talk with you maybe to expand the scope of our authority.

Senator CRAIG. Mr. Chairman, gentlemen, lady, thank you very much.

Senator DASCHLE. Thank you, Senator Craig.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. Mr. Secretary, I am very impressed with the proposals that you have so concretely set out in front of us, and you obviously have taken a great deal of time and energy in putting this together rapidly and I appreciate that a lot. I understand that some of them are short-term, some of them are long-term; some you think you can do rapidly, others are going to take time and appropriations.

My question is, when I go home this weekend to my constituents and they ask me is it safe to go to a fast food restaurant, what do I tell them?

Secretary ESPY. I would say yes. I would say make sure the meat is cooked. Make sure that it is not red or pink in the center, make sure that the juices, if any juices flow from the meat, are clear. But, yes, I can say without a doubt that most hamburgers you eat in most fast food franchise-type establishments are absolutely safe.

Senator MURRAY. I appreciate that, and putting public confidence back together is going to be a step that is difficult for all of us. I have a couple of other questions and one of them has to do with a subject you just touched lightly on, and that is coordination between FSIS and FDA. What kind of coordination do you do? I know that they have developed some testing that can identify *E. coli*. Do you use that? Do you look at that? How do you work with them?

Dr. CROSS. Yes, we coordinate very closely with Food and Drug, particularly as we look at policy development. FDA co-chairs the National Advisory Committee on Microbiological Criteria for Foods. So as we look at policy with FDA and move down that road, we do not want to move down with separate policies. So we coordinate very closely with the Center for Food Safety and Nutrition, headed by Fred Shank and Doug Archer, whom you will hear from momentarily. But I think it could be better, and that is why I proposed to the Secretary that we form this food safety council which would be composed of all the governmental agencies dealing with food safety.

Senator MURRAY. Okay, good. I am glad to hear that. I have a specific concern on the organic spray or the acidic spray that you talked about. Are the carcasses sprayed with water?

Secretary ESPY. Yes.

Senator MURRAY. This organic spray—has it been tested? Is it effective against *E. coli*? What is the history of that?

Dr. HOLLINGSWORTH. The organic spray system we recently approved as a procedure for the meat industry allows that carcasses can be sprayed with a water mist containing an organic acid. It can be acetic acid, lactic acid, or citric acid. That organic acid has been thoroughly tested. We have a lot of scientific data to support its use.

However, while the process does reduce the numbers of pathogens and other bacteria on the surface of the meat, it does not have

a 100-percent kill effect. We have also found that the meat has to have relatively low levels of bacteria to start with for the organic acid to have a chance to work, because it has an immediate contact effect. If a carcass is heavily contaminated, the effects of the organic acid are less compared to a carcass that has a very low level of bacteria, but the organic acid will bring it down lower. It is not a 100-percent kill.

Senator MURRAY. So it does affect *E. coli,* correct?

Dr. HOLLINGSWORTH. *E. coli* is one of the bacteria that it will have an effect on, yes.

Senator MURRAY. How about the spray itself? Has it been tested for side effects and for its use?

Dr. HOLLINGSWORTH. The use of the organic acid, you mean?

Senator MURRAY. Yes.

Dr. HOLLINGSWORTH. Yes, that had been thoroughly tested. We would not have allowed its use if we did not have sufficient scientific research to support it. It is not a food additive because there is no residue left on the product. It is considered a processing aid and it can be used in slaughter plants.

Senator MURRAY. Is it being used anywhere?

Dr. HOLLINGSWORTH. Yes.

Senator MURRAY. Thank you.

Senator DASCHLE. Thank you, Senator Murray.

Senator Gorton.

Senator GORTON. Thank you, Mr. Chairman. Mr. Secretary, during the last Congress I sponsored legislation which I am sure you strongly supported in the House on the subject of backhauling. Backhauling is a trucking industry practice where they carry inedible and dangerous commodities on one leg of a roundtrip and meat on the other. During Congress' investigation, we found at least one instance where garbage was hauled in one direction and fresh beef in the other.

That legislation has now become law, but there is a notice of proposed rulemaking waiting for a signature by the Secretary of Transportation as we speak. Under law, the Secretary of Agriculture fits in an advisory capacity there. I urge you to talk to the Secretary of Transportation and get that rulemaking started as quickly as possible. Are you aware of that process?

Secretary ESPY. I am unaware of it, actually. As I go back this afternoon, I will have it come up to my desk.

Senator GORTON. Great.

Secretary ESPY. And I will call Mr. Pena to ensure he knows about it. I will have him consider signing it.

Senator GORTON. I was critical of my own administration in moving as slowly as it did, and I hope that you can get it moving rapidly.

Senator Murray and I share constituents, of course, and one of our joint constituents is Jack Richardson, who lives in the tri-city area. Jack Richardson's granddaughter is one of the *E. coli* victims, and he also is someone who has been firmly committed to looking into research on irradiation. Each of you answered my initial question on that subject very satisfactorily. I am happy to hear that it is under active consideration.

In connection with this time line, Dr. Cross, can you tell me when we might reach a conclusion from that research?

Dr. CROSS. Irradiation has been researched for 50 years. Thirty-six countries approve it; over 15 of them use it on meat and poultry. So we are talking about putting the finishing touches on the research, and it should be completed in less than a year.

Senator GORTON. Great. Thank you, thank you very much. My final set of questions is on agricultural research. Research goes on all across the country. Washington State University, for example, is researching *E. coli* bacteria and has tentatively determined that the key to controlling it lies at the level of the cattle farm—essentially at the very beginning of the farm-to-table process.

Dr. Cross, do you get the benefit of all of the research that is conducted at a place like Washington State University and does WSU have the benefit of all your information? Do you work well with these land grant colleges in reaching conclusions and making decisions?

Dr. CROSS. We are very much aware of the research at Washington State and are very appreciative of that information. We use information from any source. We have very strong support from the Agricultural Research Service and other agencies at USDA, but the university land grant system is an invaluable source. The scientists in our Science and Technology Division know where the experts are and they are in constant contact with those experts, such as Michael Doyle at the University of Georgia; wherever they are. We are not bashful. I am not saying coordination couldn't be better, but it is very good. We find that data and we use it.

Senator GORTON. Well, I thank you all for your responsiveness. Mr. Chairman, I really appreciate your inviting me to share in this hearing today and I am confident that your subcommittee and your full committee are going to take very prompt action in whatever direction you deem necessary.

Senator DASCHLE. Thank you, Senator Gorton.

Congresswoman Dunn.

Ms. DUNN. Thank you very much, Mr. Chairman, and I am very appreciative, too, of having been allowed to be included in this panel. It is particularly important to me because this tragedy has affected several members of families of my constituents and we are terribly concerned about it.

I am also very happy to have the chance to hear you in person, Mr. Secretary. I have watched you as a Congressman and I appreciate your candor and the quick manner in which you have responded to this.

I want to follow up on the question of what we should tell our constituents to do about this thing. I am especially interested not only on behalf of the health of my constituents, but also because companies like Jack In The Box are very great providers of jobs to our young people, and I am especially concerned about the loss of jobs through the occurrence of a tragedy like this.

Many of our young people start out here, learn the work ethic, learn discipline, learn what regular hours mean, and it would be tragic if those jobs were lost. How we address this issue publicly is very important, and I wonder if you have any words of advice for

those of us going back home for the next week and speaking in our press and locally about this.

Secretary ESPY. Thank you for the chance to comment on that. I was concerned about two things. One, I was concerned about containing the outbreak. That is why I went to the State of Washington as quickly as I did upon direction of our President. But I was also concerned about the outbreak of hysteria; that concerned consumers might collectively quit eating or having confidence in fast food hamburgers. That is something that can happen very quickly.

Certain things are clear. One, we can never reach a zero pathogen level. Pathogens exist in warm-blooded animals, pathogens exist in raw meat. We will do everything we can do to reduce these levels, but we are not sterilizing meat, and that includes hamburger.

As we attempt to get a hold on it, though, we have already done a lot of things. We already know a lot about it. If you cook the meat to 155 degrees, you will eliminate this bacteria completely. That is the standard already in the State of Washington, as well as other places.

I don't accuse anyone or any industry or any company of anything. I say to the American public that in most places it is completely safe to eat commercial hamburgers. If you like your meat raw or very rare, you assume the risk that these pathogens continue to exist. If you like steak tartar, you assume the risk. But most hamburgers are cooked well done in these commercial establishments and that is completely OK.

Ms. DUNN. Thank you very much, Mr. Secretary. I have another question regarding overlapping jurisdictions. I sit as a member of the Joint Committee on Congressional Reform and this is something we are running into again and again. Can you assure us that there is a way to effectively coordinate the local, the State and the Federal jurisdiction to come up with the best answer and thus a coordinated plan?

Secretary ESPY. Again, I have been there for 15 days, but if I can use Washington State as a model for the degree of cooperation that I have seen between the FSIS at the Washington level, the CDC in Atlanta—the Centers for Disease Control, and the Washington State Health Authority, it has been completely harmonious. I suggest to all of the other health departments and regional authorities looking on today or listening to us that that is the standard I would like to follow.

Ms. DUNN. Thank you.

Senator DASCHLE. Thank you, Congresswoman Dunn.

Mr. Secretary, we have kept you now for nearly two hours and we appreciate very much your willingness to share your thoughts and your plans. We are very grateful. At some point yet this year, I would like to bring us back together to assess our mutual progress and to consider what might be done within the Congress, and I reiterate the thanks of this subcommittee as we wish you well in the task ahead of you. It is an important task and you have laid out your challenges and the responses to those challenges extremely well. We thank you.

Secretary ESPY. Thank you, sir.

Senator DASCHLE. Dr. Cross, if your schedule would allow, I would very much like for you to remain in order for all witnesses to come back to the table at the end of the hearing for additional discussion, and I appreciate very much your coming.

Dr. CROSS. Mr. Chairman, I am at your disposal.

Senator DASCHLE. Thank you.

Dr. CROSS. Thank you.

Senator DASCHLE. Our next witness is Mr. Robert Nugent, the president and chief operating officer of Jack In the Box, from San Diego, California. If Mr. Nugent could come to the table at this time, we will take his statement. We are pleased that you are here and we welcome you. We invite you, Mr. Nugent, to proceed with your statement at this time. The entire text will be made part of the record if you care to summarize.

STATEMENT OF ROBERT J. NUGENT, PRESIDENT, JACK IN THE BOX, SAN DIEGO, CA

Mr. NUGENT. Thank you, Mr. Chairman. Members of the subcommittee, my name is Bob Nugent. I am the president of Jack In the Box, and I appreciate the opportunity to appear before you today to discuss this tragic event, our reaction to it, and to review with you the Federal Food Safety Program.

I am going to repeat some things that have been said today, and I apologize for that. A number of people, mostly children, recently became ill after eating contaminated meat at some of our restaurants. Tragically, two have died and two remain in critical condition.

Words cannot express my sorrow or the sadness of our employees. Our hearts ache for the families and the friends of the young boy and girl who died and we pray for the recovery of those who are still ill. There is always much soul-searching after such a tragedy, but we recognize that no amount of reflection can minimize the pain or undo the loss. Our task is to learn from our pain and give our guests the protection they deserve.

Jack In The Box has moved quickly to meet this challenge. We suspended hamburger sales, gathered and inspected the meat that may have been contaminated, and once we determined which meat was contaminated, it was isolated and it will be destroyed. Although our cooking procedures meet all Federal standards, we have increased cooking time and cooking temperature for our hamburgers and retrained our grill chefs as part of our efforts to protect public health and safety. We also have offered to pay the medical expenses of those who may have become ill after eating at one of our restaurants.

But it is important to note that the contaminated meat that was infected by the *E. coli* 0157:H7 bacteria before delivery to our restaurants had passed all USDA inspections. Every one of our chefs had carefully followed all Federal food preparation standards. Still, many of our guests became ill.

The Centers for Disease Control reports that some 20,000 cases of infection from *E. coli* 0157:H7 occur every year, and every year some of these outbreaks are traceable to contaminated food that is served in restaurants, hospitals and other institutions. Clearly, the

USDA meat inspection system and Federal food preparation standards are not providing the protection Americans deserve. Better safeguards are needed.

We are determined to work with you to guard the health and safety of our guests and all American consumers. As a first step, we have initiated an investigation of the outbreak. We have also retained a number of independent experts to evaluate our internal food preparation procedures and to assess external testing methods in order to help Federal and State officials establish appropriate industry standards for slaughtering and processing beef.

I have three recommendations that I would like to offer today. First, I urge that we embark on a research program or feasibility study to see if we can detect this strain of bacteria in infected animals at the farm level to keep them from entering the food chain.

Second, I recommend new procedures at the slaughter and processing steps in the food supply chain. Inspectors at the time of slaughter look at, feel and smell the meat. However, this bacteria is invisible and cannot be detected through these methods. Therefore, I urge the USDA to implement microbial testing at the time of slaughter and processing.

Finally, and perhaps most important, we should immediately undertake research that will develop a treatment for this terrible disease that hits our children particularly hard. *E. coli* 0157:H7 creates a poison that attacks children and could be stopped if only we had the right antitoxin.

Mr. Chairman and members of the subcommittee, I reiterate our deep concern and sympathy for all those who have been affected, and our resolve to work with you and other Federal, State and local officials to ensure this never happens again.

Thank you for letting me appear here today.

Senator DASCHLE. Thank you very much, Mr. Nugent, for your opening remarks. You have noted publicly that Jack In The Box was not cooking its meat in compliance with Washington State standards; that the temperature was approximately 120 degrees when Washington State requires temperatures at 155 degrees Fahrenheit. Is that correct?

Mr. NUGENT. Mr. Chairman, our cooking procedures have been in place for many, many years, at least since 1976, and were designed to ensure that the internal cooking temperature of our hamburger patties was 140 degrees. We conduct cooking studies, and in the studies conducted for 1992, the average internal temperature was 154 degrees.

Senator DASCHLE. Is the Washington State standard 155?

Mr. NUGENT. Yes, it is.

Senator DASCHLE. So you were below the Washington State standard. The degree to which you were below is to be determined.

Mr. NUGENT. Correct.

Senator DASCHLE. As I understand it, Washington State health officials determined by back-tracking that the meat had been cooked to 120 to 130 degrees, but you say it was 154?

Mr. NUGENT. I have not seen the report. I know there was one report in the paper that indicated a particular store had the temperature taken by a health inspector that was 138 to 142 degrees. Our investigation of that particular incident found that our written

procedures were not allowed to be performed at the time that particular temperature was taken. Had the grill chef been able to perform the procedures as written and as he had been trained, I am confident that that temperature would have been in excess of 155 degrees.

Senator DASCHLE. We were informed that as long as 10 days after the notification of this outbreak that some restaurants were still not cooking hamburgers at regulation temperatures. Is that accurate?

Mr. NUGENT. The answer I just gave you with respect to the 138 to 142 degrees was in that same time frame that you are referring to, and it is my belief that the health inspectors from King County where these temperatures came from were not, in fact, allowing our employees to exercise the cooking procedures. Had they been, those temperatures would have been in excess of 155.

Senator DASCHLE. Can you assure the subcommittee that all proper cooking procedures are being adhered to and continuously, rigorously monitored?

Mr. NUGENT. Yes, I can assure you with a high degree of confidence that that is the case.

Senator DASCHLE. At what temperature are you frying your food today?

Mr. NUGENT. The average internal temperature of the hamburgers now exceeds 163 degrees.

Senator DASCHLE. 163. Are you conducting any ongoing microbiological tests to ensure the hamburger is free of this form of *E. coli*?

Mr. NUGENT. We now require that our new meat processor and one of our existing meat processors conduct the additional microbiological tests for *E. coli* 0157:H7.

Senator DASCHLE. To what extent have you been in contact with competitive fast food restaurants to determine their compliance with these procedures and their interest in following some universal process of cooking as well as inspection?

Mr. NUGENT. I have not talked to any of my colleagues in the industry, but I hope to do that.

Senator DASCHLE. Senator Craig.

Senator CRAIG. Thank you, Mr. Chairman. Mr. Nugent, we appreciate your coming before the subcommittee and appreciate the difficulties involved. I accept, as I think we all do, the sincerity of your concerns.

How often does Jack In The Box inspect its facilities? What is the routine of inspection that goes on internally, not externally by State or local authority?

Mr. NUGENT. Our internal inspection program provides, on average, 52 inspections per year, and there are two different kinds of inspections. We have a staff of 30 inspectors that do nothing but conduct unannounced audits of each of our restaurants, both franchise and company. These audits measure adherence to the standards in the areas of quality, service, cleanliness and friendliness. That audit occurs once every 4 weeks, or 13 times a year. It takes approximately an hour and 15 minutes to an hour and a half. The result of that audit is scored and then rolled up into a region, division and system score.

The other group of people that we have on our payroll consists of about 90 people who anonymously conduct inspections of the restaurants from a consumer's point of view, and those inspections occur, on average, 3 times for every 4-week period. They also are scored, rolled up into a score for the system. This is the basis by which a good percentage of our managers' incentive compensation is based.

Senator CRAIG. Does that inspection include going to the grill and looking at the burger and testing to ensure it is being cooked properly?

Mr. NUGENT. The inspection focuses very heavily on temperatures and time. It has not focused on cooking a hamburger and inspecting to see the degree of doneness or measuring the internal temperature.

Senator CRAIG. That has not been done?

Mr. NUGENT. Those studies occur at corporate office, in our laboratory at corporate office.

Senator CRAIG. How many different kinds of grills or frying devices are used in the fast food industry today?

Mr. NUGENT. There are essentially two different kinds. There is the flat grill, plate grill, that is heated, and the chain broiler that is used by some of the competition.

Senator CRAIG. Do you use the flat grill?

Mr. NUGENT. Yes.

Senator CRAIG. I have been in and out of your establishments and many others, as most Americans have over the years. We all know there are peaks in the work cycle of the day and one of those peaks probably occurs in the lunch hour. Another is when people are seeking their evening meals.

You heat your grill up and you load it up with burgers, frozen, I assume. So you have a frozen patty of raw hamburger meat on a grill; load that grill up, begin frying. The temperature of that grill drops dramatically, doesn't it?

Mr. NUGENT. The cooking temperature of our grills at lunch and dinner is 375 degrees. The average length of the grill in a Jack In The Box is six feet and it has six burners, one per foot. Each burner is U-shaped with a probe down the center. That probe is hooked into an electric device, an electric black box, if you will, which calibrates the temperature of the grill.

If you put a frozen patty on a 375-degree lane and the temperature underneath drops one degree, the burner comes on and the burner stays on until the temperature hits 380 degrees, the set point at which it shuts it off. These devices have been in our restaurants for years and have proven to be very reliable and very effective.

Senator CRAIG. Even though the grill is loaded up patty to patty with frozen product it doesn't drop below 370 or 375? Isn't there normally a sudden, sharp drop in temperature when you put a frozen unit on top of your grill?

Mr. NUGENT. I can tell you that the minute it hits 374, one degree below the prescribed level, the burner comes on, and is very effective in immediately bringing it back up—as long as the plate has been heated to its prescribed level in the first place——

Senator CRAIG. Is there a timing mechanism that tells that grill chef how long that patty should cook?

Mr. NUGENT [continuing]. Yes. We have timers above the grill and the moment the patty is placed on the grill the grill chef will then hit the appropriate button. If it's for a regular hamburger patty, that timer will start and run for one minute and 15 seconds and then it will make a sound. That sound indicates it is time to turn the patty to a new hot spot on the grill, and it allows approximately five seconds to do that. Once it is turned, it times for another minute and 15 seconds and sounds again, telling the grill cook to make one more turn of the patty, probe the center, make a visual inspection for any pink and ensure that the meat juices coming out are clear.

Senator CRAIG. Is there any connection between the timer and the temperature of the grill?

Mr. NUGENT. No, they are not linked, as they would be on our fryer timers, for example. We have fryer timers where that is the set-up, where the time will be extended if the grill temperature or the fryer temperature is lower.

Senator CRAIG. So, I come in at 3:00 in the afternoon. My hamburger might be fried singularly on a grill because of traffic or lack thereof, versus during the noon hour when my hamburger is one of many hamburgers on a grill at the same time. The procedure to assure that it arrives at the right temperature, the right cooking consistency, the right fluids flowing from it, is no longer automated but rather is visual on the part of the chef?

Mr. NUGENT. The visual inspection occurs whether you come in at lunch or you come in at midday.

Senator CRAIG. That isn't my question. I assumed that was the case. I mean that the mechanism itself—an integral part of the mechanism, and therefore the frying, the proper frying of the meat, happens to be the chef?

Mr. NUGENT. A very integral part, yes.

Senator CRAIG. It is not automated?

Mr. NUGENT. To answer what I think your question is, the timer and the temperature of the grill are not linked.

Senator CRAIG. The linkage is the chef?

Mr. NUGENT. The linkage is the chef, exactly.

Senator CRAIG. Do you make internal temperature inspections?

Mr. NUGENT. Yes, each restaurant staff performs continual inspections daily.

Senator CRAIG. How do you do that?

Mr. NUGENT. After cooking we remove the patty and take temperature readings in 4 different quadrants.

Senator CRAIG. Every patty?

Mr. NUGENT. Not every patty, no.

Senator CRAIG. What is the random approach that you use?

Mr. NUGENT. I am sorry I don't have that precise information for you, but it is on a basis that gives us confidence that the temperature of the grills is correct, that the procedures are in place, and that there is a very high degree of awareness on the part of all of our people in the kitchens.

Senator CRAIG. Well, Mr. Chairman, I don't have any further questions of Mr. Nugent. We appreciate your being here this morn-

ing and we will work with the industry to create an environment where this won't happen again.

Mr. NUGENT. Thank you.

Senator CRAIG. Thank you.

Senator DASCHLE. Thank you, Senator Craig. Just a couple of follow-ups to your answers to Senator Craig. One concerns the uniform temperature of the heating unit itself. Is the temperature uniform throughout the entire heating surface?

Mr. NUGENT. All burners are set to achieve a 375-degree temperature for lunch and dinner.

Senator DASCHLE. But the burners don't cover the entire heating surface?

Mr. NUGENT. The grill is set up to provide overlap. There are no cold spots.

Senator DASCHLE. So it is a uniform heating temperature across the entire surface?

Mr. NUGENT. Yes, that is correct.

Senator DASCHLE. I misunderstood your answer to my question about the internal temperature. I was asking about the reported disparity between what you indicate to be the temperature of the meat that was consumed and what the Washington Health Board indicated was the temperature. You said it was 154. They had indicated that it was somewhere between 120 and 130 degrees.

If we were not monitoring the internal temperature of the patties at the time, as you are today, what basis do you have for any confidence in knowing what the temperature was for those particular patties?

Mr. NUGENT. I have no way of knowing the precise temperature of those particular patties.

Senator DASCHLE. So it could be anywhere from 100 degrees to 160 degrees?

Mr. NUGENT. No, I don't subscribe to that belief. The combination of time and temperature produces an internal temperature for a patty. There could be some variance. The variance would be a function of how hard or how frozen a particular patty is, if there are any air pockets in it. But beyond that, the patties are very uniform in size and the cooking studies that we conduct at our corporate headquarters are taken from random samples from our beef supplier. And so we are cooking on the same grill at the same time with the same patty and we should receive the same results.

Senator DASCHLE. Given all of that, and given the Washington State standard of 155 degrees, and that being sort of State law, why was it not the policy of the company to have a range of temperatures that exceeded 155 to ensure that pathogens such as this would not be present in the food consumed?

Mr. NUGENT. The cooking procedures in place at the time of this incident did comply with the Federal regulation of 140. Our internal cooking temperatures indicated 154. We intended to create a procedure that exceeded what we thought were the regulations.

Senator DASCHLE. You were not aware of the Washington State regulation of 155?

Mr. NUGENT. We were not aware of the Washington State regulation.

Senator DASCHLE. Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. I appreciate the questions that you have asked. I just have a small follow-up. The temperature of the patty depends on the burner heat as well as the time that you flip it over and a visual inspection. That tells me that your employee is very integral to the safety of the individual hamburger. How do you train them? What training do they have for that required visual inspection?

Mr. NUGENT. Our employees receive training two ways. One is a video training system that is in each one of our restaurants and they go through that. We have training aids——

Senator MURRAY. Is that required training?

Mr. NUGENT [continuing]. Yes. We have written training materials that we ask the management of the restaurant to review with all employees, and on-the-job training that is conducted by the restaurant management for all employees. The step that was added as a result of this incident is the visual inspection, and it is really a fairly simple, common-sense step—to probe the inside of the patty to ensure that there is no pink and that the juices coming through are clear.

Senator MURRAY. The chef is responsible for doing that, correct?

Mr. NUGENT. Correct.

Senator MURRAY. OK. Do you have any 16- or 17-year-old chefs, or do you have to be over 18 to——

Mr. NUGENT. No. Some are 16 and 17.

Senator MURRAY [continuing]. They are directly responsible for doing that last visual check?

Mr. NUGENT. Yes.

Senator MURRAY. Thank you. Thank you, Mr. Chairman.

Senator DASCHLE. Congresswoman Dunn.

Ms. DUNN. Thank you, Mr. Chairman. I'm concerned by the line of questioning we have been taking here. Mr. Nugent, we seem to be talking about minimums a lot. What are you doing above the minimum to make sure that our children can go into Jack In The Box and know that their lunch or their afterschool snack is going to be safe?

Mr. NUGENT. The procedures that we have in place throughout our chain make us very confident that the internal temperatures far exceed the 155-degree minimum. Studies are ongoing, as they will be, and the most recent indication is that we are at 163 degrees. I feel very confident that it is completely safe to eat at Jack In The Box.

Ms. DUNN. Thank you.

Senator DASCHLE. Mr. Nugent, let me just follow up one more time because I am most troubled by the practices, and I don't mean to single you out. I am sure that there are other fast food restaurants that are analyzing their own practices right now. I assume that Jack In The Box has microbiological researchers on staff researching the different applications of heat to bacteria, is that correct?

Mr. NUGENT. We have a technical staff, yes.

Senator DASCHLE. A technical staff. Would you not expect a technical staff in Jack In The Box or McDonald's or any one of the excellent fast food restaurants to have come to some conclusion about the application of heat toward those pathogens without having to

rely on State or Federal regulation to tell you what it is you must do to make sure we eliminate the hazards of *E. coli*?

Mr. NUGENT. Mr. Chairman, let me respond to that by saying that we started in business in 1950, and for 42 years we have a system for cooking that has enabled us to serve safe, wholesome and good-quality products to hundreds of millions of customers. We have served hundreds of millions of hamburgers and we constantly are evaluating those procedures to ensure that we are meeting our obligations to our customers and public safety. Historically, we have relied upon the Government and our suppliers to provide information that would suggest that we need to make adjustments in our standards.

Senator DASCHLE. You have relied upon the Government and your suppliers. I would think that there would have been some notification of a regulation of that import saying, look, we have determined that to kill all of the *E. coli,* the bacteria, the pathogen, you have to have an internal meat temperature of at least 155 degrees.

That is such a basic part of handling an edible product that it should be imperative for a company to determine, by whatever means necessary, whatever information was available, the adequate safety. I underscore what you said about your record. It is commendable, as are so many of the records of our fast food chains, but obviously it only takes one case like this to destroy an otherwise impeccable record.

I am curious as to what goes through the minds of those executives making decisions like this when it comes to something as important as this; that is, the standards that must be set to ensure adequate confidence about the reliability of the products they are serving.

Mr. NUGENT. Mr. Chairman, I wish I had known about the Washington State regulation in May of 1992 when it was established; not in 1986, as Senator Leahy suggested, but May of 1992. That is when it was established. I wish I had known about the outbreak in Walla Walla where there were two deaths in 1986. I didn't.

I have instituted a full-scale investigation. We are pulling records from all of our restaurants. We are interviewing all of our employees to find who knew what and, if anybody knew anything, why didn't our corporate headquarters know it. At this point, all I can tell you is that I didn't know it. I wish I had.

Senator DASCHLE. Well, again, Mr. Nugent, we are very pleased that you could share your experience and your thoughts with us this morning. I don't know what your schedule is, but if it would allow for you stay for the rest of the hearing in order to return to the table at the end, I would appreciate it. But I fully respect your schedule and appreciate the time you have already provided, so we thank you.

Mr. NUGENT. Thank you, Mr. Chairman.

[The prepared statement and a letter of Mr. Nugent follows:]

PREPARED STATEMENT OF ROBERT J. NUGENT, PRESIDENT, JACK IN THE BOX, SAN DIEGO, CA

Mr. Chairman and members of the subcommittee, my name is Bob Nugent. I am President of Jack In The Box. I appreciate the opportunity to appear before you

today to discuss recent tragic events, our reaction to them, and to review with you the Federal Food Safety Program.

Recently, our company was notified by Washington State officials that a number of children became seriously ill from ingestion of meat contaminated with the *E. coli* 0157:H7 bacteria. Sadly, one child who was our customer has died. Another remains in intensive care. On behalf of myself and my company, we are deeply sorry that these events have occurred, and we sincerely regret their impact on our customers and their families. We have extended our sincere sympathies to our customers who have been affected and have offered to pay all medical expenses flowing from these illnesses.

These developments touch us all. As you can well imagine, we also have children and grandchildren who consume our products. While we feel that we at all times have taken the necessary steps to ensure compliance with Federal regulations in place at the time of these events, it is our intent to do everything within our power to rectify the problem and live up to our responsibilities to those affected. We understand that several children have been released from hospital care and a number of children continue to require dialysis treatment. We are receiving reports of their condition and are monitoring their progress with hopes that these children will recover from their illness. Our thoughts and prayers are with them.

When we first learned of this outbreak, and the potential connection between these illnesses and food served through our company, we were horrified and alarmed. Horrified, because we believed that the beef we received from our suppliers was fit for human consumption. Alarmed, because despite our strict adherence to the Federal standards and the lack of any indication that such illness had ever resulted from ingestion of one of our products, patties which were distributed were unfit for human consumption and potentially hazardous to the American consumer.

Jack In The Box has been in the food service industry since 1950. As you know, efforts to provide safety standards for meat processing and handling have been ongoing since the 1800's, with the first model standards issued by the FDA in the 1930's. We have complied strictly with those standards, including the most recent revisions in 1976. In fact, the history of our company's compliance with those regulations is verified through numerous evaluations conducted by Federal, State and local governments.

In the past, our procedures, and our compliance with them, have ensured that the product we receive and serve has been healthy, wholesome and fit for human consumption. In assessing the adequacy of our procedures, and their continued viability, we have relied on both the Government and our suppliers to notify us if and when information is obtained which suggests that current standards may not provide American consumers with an adequate level of safety. Because of this outbreak, we are committed to working with you as you seek to increase safety standards for the public.

In order to properly assess the advisability of new standards, a thorough analysis and investigation of what has happened must take place. When we originally were notified of the outbreak, we immediately sought to identify any potential connection our company had to the problem. We were informed that many of the children afflicted with this recent illness were customers of our establishment. Many other outbreak victims were not our customers. Regardless, we spared no effort to isolate and recall any product served in our outlets which may have been contaminated.

As a result of our recall, we were able to identify and isolate the contaminated batch of hamburger patties, which was tested by Washington State and Federal agencies. These tests, we are told, confirmed that some patties which we received in their frozen state were contaminated with unacceptably high levels of *E. coli* 0157:H7 bacteria.

Our response was swift. Despite the fact that our cooking procedures adhered to Federal regulations, we increased the cooking time of our hamburger products and retrained our food preparation staff in order to ensure that we were doing everything possible to provide for the public's safety. In addition, we have established relationships with experts in the field to assist us in reevaluating not only our internal preparation procedures but also external testing procedures in order to assist the Federal Government, and any States who seek our assistance, in the development of new industry standards for the processing of beef.

It is our understanding that the U.S. Department of Agriculture's Food Safety & Inspection Service currently requires some tissue examination during the slaughter of animals. Such testing is done by either visually observing the meat or actually feeling the meat. No tests are routinely performed for this bacteria or any other bacteria in fresh meat, though we understand that the Food and Drug Administration has the ability to perform microbial studies in the field which would detect the

presence of harmful bacteria. These kinds of field studies can perhaps play a useful role in early detection of potential contamination.

Historically, it has been recognized that contamination originates in the field, slaughterhouse, and processing plants. Accordingly, we believe that the Federal Government should consider requiring the use of beef hazard analysis and critical control point systems within slaughter and processing facilities. We urge you to consider requiring intensified efforts to locate infected animals at the farm level to keep them from entering the food chain while they harbor harmful bacteria.

Our joint charge—we as food providers and you as policymakers—is to design a system of inspection and regulation which will provide for the identification of harmful bacteria prior to distribution to consumers.

Additionally, we have followed the Federal food preparation regulations established in 1976 providing for the internal temperature to which ground beef is required to be cooked in order to kill all bacteria. However, it would seem from the conflicting standards recently implemented by Washington State that the Federal regulation may need to be reexamined. We understand that the FDA has issued an emergency guideline raising cooking temperatures.

The State of Washington has raised its temperature from the federally mandated internal cooking temperature of 140 degrees to its own standard of 155 degrees. While it appears that there has been some confusion regarding the implementation of the 155 degree cooking standard, what is clear is that a uniform national standard is necessary. We believe that 155 degrees may be an appropriate standard, based upon our review of literature concerning the cooking time and temperature required to kill dangerous bacteria.

Notwithstanding any steps taken in this respect, we should not believe that increased temperatures will alone suffice to protect the public. When the Federal regulations were initially issued, it was felt that the internal cooking temperature of 140 degrees would be sufficient to kill any bacteria which may have affected the beef during slaughter or processing. Subsequent experience seems to justify a higher standard, which we have already implemented in all of our outlets. However, because of the importance of the issue, microbial testing as an additional safeguard should be considered to further assure the safety of the products.

Most importantly, we encourage you to require the various regulatory agencies that regulate foods from farm to consumer to act in concert in forming uniform national regulations and procedures which will prevent a tragedy such as this from occurring.

Mr. Chairman and members of the subcommittee, we sincerely appreciate the opportunity to appear before you today to discuss these tragic events and possible steps to establish new standards or procedures to ensure the safety of our Nation's meat supply.

Senator DASCHLE. Let me call upon our third panel, Dr. Paul Blake, the Chief of the Enteric Diseases Branch of the Division of Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention (CDC) in Atlanta; and Dr. Douglas Archer, the Deputy Director of Programs for the Center for Food Safety and Applied Nutrition, Food and Drug Administration, Rockville.

Gentlemen, we are pleased that you could be with us. Let me remind you that the entire text of your statements will be made part of the record if you wish to summarize them. Dr. Blake, we will take your statement at this time.

STATEMENT OF DR. PAUL BLAKE, CHIEF, ENTERIC DISEASES BRANCH, DIVISION OF BACTERIAL AND MYCOTIC DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), ATLANTA, GA

Dr. BLAKE. Thank you, Mr. Chairman. I am Paul Blake, Chief of the Enteric Diseases Branch of the National Center for Infectious Diseases, Centers for Disease Control and Prevention. I am pleased to respond to the subcommittee's invitation to provide testimony on infections caused by *Escherichia coli* 0157:H7.

This strain of *E. coli* is an emerging cause of foodborne disease. Its importance as a human pathogen appears to have been increasing since its discovery in 1982. Infection with *E. coli* 0157:H7 may result in mild diarrhea, severe bloody diarrhea, hemolytic uremic syndrome, kidney failure, and death. Most often, the organism produces hemorrhagic colitis with severe abdominal cramping and bloody diarrhea.

In less than 10 percent of cases, the organism produces the hemolytic uremic syndrome, or HUS, with destruction of red blood cells and acute kidney failure. HUS is the most common cause of acute kidney failure in children in the U.S. Approximately two to five percent of affected children die, and this disease can also lead to long-term problems with high blood pressure and chronic kidney failure.

E. coli 0157:H7 was first recognized as a human pathogen in 1982 when CDC investigated outbreaks of bloody diarrhea in Oregon and Michigan. We implicated hamburgers from a fast food restaurant chain. Since then, investigations of 15 outbreaks of *E. coli* 0157:H7 have taught us a lot. The organism can spread person to person in day care centers. It can cause devastating outbreaks in nursing homes. It can be transmitted by contaminated roast beef, as well as by ground beef. It can spread through municipal water supplies. It can be acquired by swimming in a contaminated lake, and it can be transmitted by apple cider.

Ground beef has been the most commonly implicated source for this pathogen, and raw milk has also been a source of infection. In several outbreaks, ground beef was traced back to dairy cattle sources and *E. coli* 0157:H7 organisms were isolated from live healthy animals on these farms. Although we know that dairy cattle are an important reservoir for this organism, there are many unanswered questions about its etiology on dairy farms and about the slaughter and processing practices that contaminate ground beef.

The current outbreak of *E. coli* 0157:H7 illness in Western States is the largest ever reported. It was detected in mid-January when children with hemorrhagic colitis and HUS were admitted to Washington hospitals. By January 15, more than 25 cases of *E. coli* 0157:H7 infection had been documented in the Puget Sound area.

By January 17, health authorities had implicated hamburgers served by a fast food restaurant chain. The implicated lots of hamburger were produced in November 1992. Their distribution suggested that Nevada, Idaho and Southern California might also be affected. *E. coli* 0157:H7 was isolated from implicated hamburger.

To date, almost 350 cases of bloody diarrhea have been reported in Washington State. Twelve persons with documented infection have been reported in Idaho, and Nevada reported 30 cases of bloody diarrhea during January. Cases of bloody diarrhea and HUS occurred in the San Diego area in December and January. Teams are investigating the outbreaks and tracing the implicated meat back through boning plants and slaughterhouses to farm sources.

Turning to surveillance, State health departments determine which diseases must be reported to them by physicians and laboratories and which diseases the States will report to CDC. At the spring meeting of the State and territorial epidemiologists, we will

propose making *E. coli* 0157:H7 reportable to CDC. It currently is not. At present, *E. coli* 0157:H7 infections are reportable to local and State health authorities just within the State in 10 States. At least nine other States are planning to add this organism to their list of reportable diseases.

Control and prevention of *E. coli* 0157:H7 will require better surveillance, but we also need a better understanding of the etiology of the organism. We need to control contamination of food products at the source and during processing, and we need to educate consumers and the food service industry.

As stated in the recently released Institute of Medicine report "Emerging Infections and Microbial Threats to Health in the United States," we can expect new infectious diseases to continue to emerge and spread in the United States as a result of microbial evolution and technological change.

Mr. Chairman, with your permission, I would like to request that the Summary of the Institute of Medicine report be made part of the record of this hearing.

Senator DASCHLE. Without objection, it will be made part of the record.

[The Summary referred to by Dr. Blake is retained in the subcommittee file.]

Dr. BLAKE. *E. coli* outbreaks highlight the need for rapid epidemiologic assessments of new or unusual diseases and for an effective network of State and national public health agencies and laboratories, as was recommended in the Institute of Medicine report.

Foodborne diseases continue to be a major and growing public health problem in the U.S., producing millions of illnesses and thousands of deaths in this country every year. However, as we recently have observed with the reemergence of tuberculosis and measles, an adequate level of surveillance and other public health efforts is essential to prevent increased incidence of acute disease, increased numbers of persons with resulting chronic disease, and increased costs of control.

Thank you for the opportunity to testify before the committee. I would be happy to answer any questions you may have.

[The prepared statement of Dr. Blake follows:]

PREPARED STATEMENT OF PAUL BLAKE, CHIEF, ENTERIC DISEASES BRANCH, DIVISION OF BACTERIAL AND MYCOTIC DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

I am Paul Blake, Chief of the Enteric Diseases Branch of the Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am pleased to respond to the subcommittee's invitation to give a statement on infections caused by *Escherichia coli* 0157:H7.

This strain of *E. coli* is an emerging cause of foodborne disease. It was first determined to be a human pathogen by CDC in 1982, and its importance as a human pathogen appears to be increasing. Infection with *E. coli* 0157:H7 may result in mild diarrhea, severe bloody diarrhea, hemolytic uremic syndrome, kidney failure, and death. In my statement I will review our knowledge of the epidemiology of disease caused by *E. coli* 0157:H7, review the status of surveillance for this infection, and comment on control and prevention efforts.

E. coli 0157:H7 can produce a spectrum of clinical manifestations ranging from asymptomatic infection to death. Most often the organism produces a distinctive syndrome termed hemorrhagic colitis, which is characterized by severe abdominal cramping accompanied by bloody diarrhea but little or no fever. The typical duration of illness is 5–10 days. In less than 10 percent of cases, the infection causes de-

struction of red blood cells (hemolysis) and acute kidney failure (uremia). This complication, referred to as the hemolytic uremic syndrome, or HUS, is seen most commonly when *E. coli* 0157:H7 infection occurs in children under age five or among the elderly. HUS is recognized as the most common cause of acute kidney failure in children in the United States. The disease often requires prolonged hospitalization in critical care units. Approximately 2–5 percent of affected children die, and it can also lead to long-term problems with high blood pressure and chronic kidney failure.

E. coli 0157:H7 was first recognized as a human pathogen in 1982 when CDC investigated outbreaks of bloody diarrhea in Oregon and Michigan. In both States disease was linked to eating contaminated hamburgers from a fast food restaurant chain; the organism was isolated from a sample of ground beef from the restaurant chain.

Since the original 1982 outbreak, CDC, in collaboration with State health departments, has investigated 15 outbreaks of *E. coli* 0157:H7 infection in the United States. These investigations have expanded our knowledge of the epidemiologic and clinical features of *E. coli* 0157:H7. As examples, a 1984 CDC investigation in North Carolina was the first to demonstrate spread of the organism among children through fecal-oral transmission in a day care setting. Another 1984 CDC investigation in Nebraska documented the devastating consequences of contamination by *E. coli* 0157:H7 in a nursing home. In 1986, CDC identified a dairy animal reservoir as a result of investigations of outbreaks in Minnesota and Washington State. A 1988 outbreak investigation in Wisconsin was the first to link infections with contaminated roast beef, while a 1990 outbreak in Missouri was the first to show waterborne transmission. In 1991, transmission of *E. coli* 0157:H7 from swimming in a contaminated lake in Oregon was demonstrated, and in the same year CDC linked infection to drinking freshly pressed apple cider in Massachusetts.

Although these outbreaks demonstrate a number of food vehicles for transmission of *E. coli* 0157:H7, ground beef has been the most commonly implicated source for this pathogen. Before the current outbreak, *E. coli* 0157:H7 outbreaks have been linked to ground beef consumption in Nebraska, Utah, Washington State, Minnesota, and North Dakota in addition to the original outbreaks in Oregon and Michigan. A small cluster of rural cases in Wisconsin was linked to drinking raw milk, as was a 1985 outbreak in a Canadian kindergarten class. Finally, a 1985 study of sporadic cases of *E. coli* 0157:H7 infection in Seattle found associations with consumption of both raw hamburger and raw milk.

In several outbreaks, ground beef was traced back to dairy cattle sources, and *E. coli* 0157:H7 organisms were isolated from live healthy animals on these farms. The organism can live in the intestines of these animals without producing disease. These findings have led to the conclusion that dairy cattle constitute a major reservoir for transmission of *E. coli* 0157:H7 to humans. However, we do not fully understand the etiology of the organism on dairy farms, its prevalence and geographic distribution, and why it is present on some dairy farms and not others. We also lack information on slaughter and processing practices that result in contamination by this microorganism of ground beef produced from culled dairy cattle.

The current outbreak of *E. coli* 0157:H7 illness in the Western States is the largest which has been reported to date. Although its size and its multistate nature make this outbreak unique, it shares many features with previously reported outbreaks. The outbreak was detected in mid-January when children with hemorrhagic colitis and hemolytic uremic syndrome were admitted to western Washington hospitals. By January 15, more than 25 cases of *E. coli* 0157:H7 infection had been documented in the Puget Sound area. By January 17, an investigation by a team of local and State health authorities, including a CDC epidemiologist assigned to the Washington State Health Department, had implicated hamburgers served by a fast food restaurant chain as the source of infection.

Tracing of implicated lots of hamburger indicated that they had been produced in November 1992. On January 18 a recall of these lots was announced, and lots were returned from stores in Washington, Nevada, Idaho, and southern California, suggesting that patties had been served in these areas and that illness might be present there as well. *E. coli* 0157:H7 was isolated from implicated samples of hamburger after the recall had been announced. To date, almost 350 cases of bloody diarrhea have been reported in Washington State, and over 200 have been culture-confirmed as *E. coli* 0157:H7. Twelve persons with documented *E. coli* 0157:H7 infection have been reported in Idaho, and Nevada reported 30 cases of bloody diarrhea during January. Cases of bloody diarrhea and hemolytic uremic syndrome, documented to be *E. coli* 0157:H7, have also occurred in the San Diego area. The San Diego cases occurred in both December and January. CDC is currently working with State and local health departments, the USDA, and the FDA to investigate the outbreaks in

these jurisdictions, and to trace the implicated meat through boning plants and slaughterhouses back to farm sources.

Since *E. coli* 0157:H7 was first identified as a cause of human disease in 1982, CDC has made great efforts in conjunction with State and local health departments to promote control and prevention efforts for this organism. The outbreak investigations, already described, have defined the arena for prevention activities throughout the ground beef production process. CDC has also developed recommendations and educational materials to control the spread of *E. coli* 0157:H7 and other diarrhea pathogens in the day care setting. Efforts have been directed toward educating physicians about *E. coli* 0157:H7 and the need to culture stools of patient with diarrhea for this organism, especially those from patients with bloody diarrhea. CDC laboratories have developed easy and inexpensive tests to screen stool specimens for *E. coli* 0157:H7, and have developed blood tests to detect recent infection when stools cannot be cultured or illness may have resolved. CDC laboratories have developed techniques to subtype strains for epidemiologic purposes. CDC has also encouraged States to institute surveillance for *E. coli* 0157:H7.

Despite this progress, many questions about the epidemiology of *E. coli* 0157:H7 remain. The frequency of this infection is still unknown, and its geographic distribution within the United States remains undefined. Screening of stool specimens for *E. coli* 0157:H7 by clinical laboratories is not widely practiced in many areas of the United States, and many clinicians are uninformed about the importance of this organism. These factors suggest that *E. coli* 0157:H7 is greatly under-diagnosed in this country. This may in part explain the wide variation in reported cases in the areas affected by the current outbreak. Surveys in the Pacific Northwest suggest that the yearly incidence of infection may be as high as 8 cases per 100,000 population, which would translate to about 20,000 cases per year in the United States. However, these estimates require further validation.

The authority to make a disease notifiable rests with the States. State health departments determine which diseases must be reported to them by physicians and diagnostic laboratories within their borders and, through the Conference of State and Territorial Epidemiologists, which diseases the States will report to CDC. At present, *E. coli* 0157:H7 infections are reportable to local and State health authorities in ten States. These include Connecticut, Idaho, Michigan, Missouri, North Dakota, Nebraska, Nevada, Oregon, South Carolina, and Washington State. In addition, HUS, but not infection by *E. coli* 0157:H7 alone, is reportable in New Jersey. In most of these jurisdictions, reporting requirements have been instituted too recently to evaluate disease incidence or trends. Other States, including California, Indiana, Maine, Massachusetts, New Hampshire, New York, Pennsylvania, Utah, and Wyoming, are planning to add *E. coli* 0157:H7 to their list of reportable diseases. As a result of the recent outbreak, additional States are now expressing an interest in making this disease reportable. As more States institute this requirement and data are collected, a clearer picture should emerge of the scope and incidence of this infection. However, to be most effective, the reporting requirement must be coupled with wider knowledge among clinicians, appropriate testing of clinical specimens, and the ability of local and State health departments to analyze reported cases promptly and take appropriate action. CDC has contributed to this effort by widely disseminating information on the disease and the microorganism that causes it through publication of the results of its studies in the scientific literature.

In addition to better surveillance, control and prevention of *E. coli* 0157:H7 will require a better understanding of the environmental etiology of the organism, efforts to control contamination of food products at the source and during processing, and education of consumers and the food service industry on the hazards of raw or undercooked foods and proper cooking and preparation techniques. This will require continuing collaborative efforts of CDC with local and State health departments, USDA, FDA, universities, and all aspects of the food industry. In addition to publishing reports on *E. coli* 0157:H7, CDC has engaged in an active speaking campaign before medical, regulatory, producer, food industry, and consumer audiences, and has collaborated with FDA, USDA, and food industry organizations on the development of educational materials. CDC also included this strain of *E. coli* on the list of diseases transmitted through the food supply written in response to a mandate under the Americans with Disabilities Act of 1990 to provide further information and guidance to food safety regulatory officials and the food service industry.

Our experience with *E. coli* 0157:H7 illustrates important lessons. As documented in the recently released Institute of Medicine report on emerging infections and microbial threats to health, we can expect new infectious diseases to continue to emerge and spread in the United States as a result of microbial evolution and technological change. Similarly, conditions with an unknown etiology, such as the hemo-

lytic uremic syndrome, can turn out to have an infectious cause. The earlier outbreaks and the current problem highlight the need for rapid epidemiologic assessment of new or unusual diseases and for an efficient network of State and national public health agencies and laboratories, as recommended in the Institute of Medicine report, to detect the emergence of pathogens such as *E. coli* 0157:H7. Prevention also requires close multiagency collaboration, especially for organisms with potentially devastating consequences and the ability to spread rapidly.

Foodborne diseases continue to be a major and growing public health problem in the United States, producing millions of illnesses and thousands of deaths in this country every year. However, as we also recently have observed with the re-emergence of tuberculosis and measles, an adequate level of surveillance and other public health efforts is essential to prevent increased incidence of acute disease, increased numbers of persons with resulting chronic disease, and increased costs of control.

Thank you for the opportunity to testify before the subcommittee. I will be happy to answer any questions you may have.

Senator DASCHLE. Thank you, Dr. Blake.

Dr. Archer.

STATEMENT OF DOUGLAS L. ARCHER, DEPUTY DIRECTOR FOR PROGRAMS, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD

Dr. ARCHER. Thank you, Mr. Chairman. Mr. Chairman and members of the subcommittee, I am Douglas Archer. I am Deputy Director for Programs of the Center for Food Safety and Applied Nutrition of FDA. Before I begin, the Department of Health and Human Services and the FDA want to express their sympathy to those affected by the tragic events that bring us to today's meeting. The events discussed today have an additional tragic dimension because, like most foodborne outbreaks, it could have been avoided.

I am here to describe FDA's role in assisting the States in the regulation of restaurants; specifically, the temperature guidelines for cooking of potentially hazardous foods. The hamburger implicated in the recent outbreak of illness in Washington State is one such potentially hazardous food. You also asked our opinion on the value of the HACCP system as a method to reduce the occurrence of pathogenic bacteria in hamburger.

The responsibility to assure the consumer that food served in restaurants is safe and not a vehicle for the transmission of communicable disease is shared by the food industry and local, State and Federal Government agencies. Because of our finite resources, FDA generally does not regulate restaurants, but instead relies on cooperative arrangements with the States.

FDA's Retail Food Protection Program is the cooperative Federal-State effort that covers the food service, food vending and food store industries. It is the vehicle through which FDA works with the States in the regulation of foods served in retail establishments.

More than 85 State and territorial, and nearly 3,000 local regulatory agencies assume primary responsibility for monitoring retail level food operations and for assuring that the food industry is adequately protecting the consumer in the marketplace. FDA assists and supports State and local regulatory agencies by coordinating development of uniform standards, known as model codes; providing technical assistance and interpretation; developing training aids; providing training; and, upon request, evaluating State pro-

grams. The model codes provide minimum standards that we encourage State governments to adopt. States are free to add requirements as they see fit or even set higher standards. FDA's primary goal in operating the Retail Food Protection Program is the prevention of foodborne illness. We work toward this goal by establishing measures designed to reduce the likelihood of foodborne illness. Three major contributing factors to illness that we address in this program are improper holding and storage temperatures, inadequate cooking of potentially hazardous foods, and improper food handling procedures that can cause cross-contamination of food.

The recent outbreak in Washington State involves ground beef, which is just one of the potentially hazardous foods covered by the retail food code. We know that no food is totally free of bacteria unless specially processed, as is the case in canned foods and liquid infant formulas. Raw animal products naturally contain bacteria, some of which may cause human illness if the animal product is not adequately cooked prior to consumption. Ground beef is a comminuted or mixed product, greatly different from beef roasts and other so-called solid meats. It is potentially a more hazardous product because the grinding process mixes pathogens normally found only on the surface of solid meats to a relative uniformity throughout the product. This means that adequate cooking must occur throughout the hamburger in order to kill all the pathogens.

Preliminary reports indicate that the beef patties associated with the recent outbreak contained *E. coli* 0157:H7 at an as yet undetermined level. Additionally, the product may not have been cooked sufficiently in all cases in the restaurants to eliminate the microbes present in the raw product.

Factors such as cooking time, cooking temperature, and the bacterial load in the food must be considered in establishing cooking directions for potentially hazardous foods. The current FDA model food code provisions call for ground beef, like other potentially hazardous foods, to be cooked to heat all parts of the food to a temperature of 140 degrees Fahrenheit. Until now, such cooking had been considered adequate to destroy hazardous bacteria. In short, our 140-degree guidance covered the types and levels of bacteria that had been found in potentially hazardous food. Although all the circumstances surrounding the present outbreak are not yet clear, as a prudent public health protection measure FDA has provided interim guidance to Federal, State and local officials recommending that ground beef products should be cooked to heat all parts of the food to at least 155 degrees Fahrenheit.

FDA has long advised inspection personnel in State regulatory agencies that they should treat all raw meat and fish as though it contained some level of pathogens. A critical control point for reducing the hazard of raw animal products is adequate cooking to assure destruction of these pathogens. If a restaurant or other food vendor deviates from these recommendations, the safety of the product may be diminished.

Restaurants and other food vendors should systematically monitor their cooking process to assure that the time-temperature parameters are being met. During inspections, regulatory personnel should routinely verify that potentially hazardous foods are being

adequately cooked and that the establishment has initiated a procedure for routine monitoring.

While we are recommending interim measures to address the current situation, the development and application of any effective control measures must be made in context. Cooking time and temperature is only a part of the picture. While such a strategy might be effective in the case of one consumer and one meal, it does not take into account concerns arising from cross-contamination in the kitchen and mishandling of food after cooking. Ideally, pathogens would not be present in food, but short of that their numbers should be kept as low as possible. To accomplish this, control measures must be designed that go from farm to table.

The 140-degree cooking temperature recommended by FDA was adequate, considering the types and loads of microorganisms generally found in potentially hazardous food. What happened, then? One possibility is that the meat patties prepared by the meat processor on November 19 were somehow different, perhaps containing higher levels of *E. coli* than usual which might have rendered the normal cooking procedure ineffective. Another possibility is that adequate temperatures were not being achieved in some of the hamburger patties.

FDA has recommended raising the cooking temperature to 155 until the investigation of this tragic outbreak gives us insight into the causal factors.

Raw animal products will never be sterile, but that does not mean that we should not make every effort to reduce to the greatest extent practicable, or better yet eliminate, potentially dangerous microorganisms. We pledge our cooperation to USDA as it seeks to eliminate potentially dangerous microorganisms in meat as we at FDA are working to eliminate them in the foods that we regulate.

Our immediate attention will be focused on investigating this outbreak and researching the characteristics of the organism and its susceptibility to various lethal processing steps. These pieces of information are vital in the development and evolution of our model code recommendation which will eventually replace the interim guidance of January 28.

But changing the cooking temperature is only the first step in developing a comprehensive strategy to prevent a recurrence of this tragedy. A comprehensive food safety strategy must be all-encompassing, going from farm to table. It must address all points in the food chain where pathogens can effectively be controlled or eliminated.

You asked for our opinion of the Hazard Analysis Critical Control Point system, or HACCP, as a strategy for controlling the presence of pathogenic bacteria, including *E. coli* 0157:H7, in beef. HACCP was first utilized by FDA in the early 1970s to control microbiological hazards in the mushroom canning industry. After considerable refinement, FDA also applied HACCP to other food products, particularly low-acid canned foods. A continuous visual-type program would be effective for monitoring sanitation and quality, but most potential safety problems involving contaminants require laboratory analyses to detect.

HACCP requires the identification and monitoring of the critical control points in the handling and processing of food. The critical control points are the handling and processing steps that pose the greatest risk if not performed properly. Industry and the Government cooperated in the development of a HACCP system for low-acid canned foods. We understand that the Department of Agriculture has conducted some pilot applications of the HACCP system to meat processing. We are more than willing to share our experiences with HACCP with USDA as it moves forward and, in fact, both agencies are cooperating closely on developing HACCP principles for meat products in the National Advisory Committee on Microbiological Criteria for Foods.

In summary, FDA has worked closely with the States through our Retail Food Protection Program to provide guidance and practical assistance in regulating the foods offered in retail establishments. The recent outbreak of illness leads us to believe that a temporary modification to our recommendations to the States is necessary while we consider the necessity for a more formal change to the cooking standards for ground beef. We have found HACCP to be an effective system for protecting against illnesses caused by foodborne pathogens. Furthermore, we find that a system based on sampling and microscopic analysis of food with an emphasis on driving the numbers of pathogens as low as possible is effective in protecting the public from illnesses caused by FDA-regulated products.

That concludes my statement and I would be pleased to respond to any questions you might have.

Senator DASCHLE. Thank you, Dr. Archer. Just to clarify, you said that you have examined the applicability of HACCP to meat processing, and I'm not sure what you have determined thus far. Is there an application in the practices used for vegetables, and mushrooms in particular, as it applies to the criteria we lay out for meat processing?

Dr. ARCHER. Mr. Chairman, the principles of HACCP are the same regardless of where they are applied in the food chain or what type of food is of concern. The same principles, having critical control points in, say, low-acid canned food processing, would apply on the farm, in a slaughterhouse, or in a processing plant. There are certain things that contribute to the burden of pathogens in a product and critical control points established in a scientifically-based manner should control some of the problems.

Senator DASCHLE. Given the infrequent occurrence of *E. coli,* what is the feasibility of implementing a regulatory screening program like HACCP that could give us the confidence that we could effectively eliminate any one of the strains of *E. coli* from the meat system? Is it possible?

Dr. ARCHER. Mr. Chairman, HACCP principles applied rigorously should force the numbers of organisms down to a low and controllable level where cooking and later procedures will help to control them. Total elimination? No, probably not, but the lower the number or the lower the biological burden in any raw food, the less the chance becomes, quite dramatically, of anything going wrong.

Senator DASCHLE. Obviously, a microbiological inspection system would require that the product be detained prior to the distribution

and pending the outcome of the analysis. How would product detention affect meat processing and storing and handling of the meat in the interim?

Dr. ARCHER. FDA faces the same problem that other regulatory agencies do. Perishable products, in particular, pose a problem if the microbiological analysis takes from three to seven days to complete. It is not very practical to hold a perishable product that long.

On the other hand, FDA routinely detains all imported frozen shrimp in storage until the analyses are complete and we are certain that they are free from *Salmonella* and other pathogens. It can be done.

Senator DASCHLE. There is some question as to what the temperature must be to kill *E. coli.* Originally it was determined to be 140 degrees and it has now been determined that 155 degrees would give us that confidence. Is it not clear what temperature will kill most of the known *E. coli* strains?

Dr. ARCHER. Mr. Chairman, there are many, many scientific studies that have been done that give us confidence that the temperature that we have recommended, first of all, would be adequate to kill a reasonable load of this particular organism or any other that has similar heat sensitivity.

The question of temperature can't be dealt with alone. It is a temperature-time relationship. For example, there would be no rare roast beef in the United States if it had to be cooked to 155 degrees. It is a matter of a combination of a temperature of 130 degrees with a time of 121 minutes that allows you to have safe roast beef that still looks rare.

The 140-degree minimum that we set in our model ordinance, again, stated that all parts of the product would be heated to that temperature. That takes a good deal of time, and for most potentially hazardous foods, that offers sufficient protection from what we would consider normal loads. Any process can be defeated if enough microorganisms are thrown at that process. It is a matter of how many are there to start with and how many the temperature can deal with.

Senator DASCHLE. Dr. Blake, many of the reported cases of this *E. coli* appear to be in Northern States. Why is that, and what is the suspected mechanism that transmits this bacteria to cattle?

Dr. BLAKE. We don't know why the incidence of the disease appears to be higher in the north. This has been observed for quite some time now, and Canada has even more than we have along our northern tier of States and we can't explain that. We don't know if it relates to how badly the cattle are infected or how people cook their meat, or what. It isn't clear.

I am sorry. What was your second question?

Senator DASCHLE. What is the suspected mechanism that may transmit this bacteria to cattle in the first place.

Dr. BLAKE. We have a lot to learn about the etiology of this organism in cattle. Before 1982, this organism was not recognized as an important cause of disease in humans. In 1982, we went back and looked at over 3,000 strains of *E. coli* and found only one previous strain of it, and the number of outbreaks has been increasing with time. How do we explain this? It is possible that the disease is

spreading within cattle and becoming more and more frequent in the cattle population, but I don't have data on that.

Senator DASCHLE. The New York Times reported that there are approximately 6,000 cases of *E. coli* 0157:H7 reported each year. This number strikes me as very high, considering the many cases that are likely to go unreported. Are confirmed cases of this strain of *E. coli* routinely reported to the Centers for Disease Control and did the New York Times report that number accurately?

Dr. BLAKE. This disease is not being reported to CDC. The State and territorial epidemiologists determine which diseases are to be reported and not reported. Of course, each additional organism that is reported puts an additional burden on the State health departments which are already hard-pressed. This organism has become sufficiently important nationwide now that I think it is appropriate for it to become nationally reportable.

The numbers that have been used to estimate the number of cases that may occur tend to come from surveys. For example, working with the State of Washington, we carried out a survey several years back in the Seattle area with a health maintenance organization and were able to establish that among people seeking medical assistance largely for bloody diarrhea, there were quite a few of these *E. coli* 0157:H7 infections, and in that population served by the HMO there were 8 cases per 100,000 people per year.

If you extrapolate that figure to the entire United States, that would be 20,000 cases per year. There are some problems with extrapolating it because the incidence of the disease may be higher in Washington State than in some of the Southern States, and also there would be lots of people who would never be cultured because they didn't have the more severe disease. But at least we know we are talking in terms of thousands rather than hundreds or hundreds of thousands.

Senator DASCHLE. Thank you, Dr. Blake.

Senator Craig.

Senator CRAIG. Dr. Blake, in your studies and analysis, you tracked this to certain herds of livestock, cattle. Did you go beyond that? Has there been any study or comparison done as to what might cause a specific herd of cattle to carry it? What kind of husbandry practices were incorporated? Has there been a broader analysis than just tracking it through to a specific herd?

Dr. BLAKE. You tend to find the organism more in younger animals than in older animals. A survey of veal calves found the incidence was higher in calves that came from dairy herds than in calves that were raised specifically for veal. It is possible that USDA has more information on that.

Senator CRAIG. How many of these kinds of studies are you aware of?

Dr. BLAKE. A fairly small number.

Senator CRAIG. So you couldn't pull a broad base of conclusion from that yet?

Dr. BLAKE. No. Secretary Espy suggested there should be a lot more work done in that area and I concur.

Senator CRAIG. You said, "the emerging cause of *E. coli*, 1982." Is this strain relatively new? I mean, did *E. coli* 0157:H7 not exist at some time in the immediate past?

Dr. BLAKE. We looked for traces of it before 1982. We do know that it has become more and more frequent since 1982. It is difficult to put exact numbers on it because many laboratories don't test for it, but the evidence shows that it has become more common since then in the United Kingdom, in the United States and in Canada.

Worldwide, it is rarely found. They have just had an epidemic of this disease in the southern part of Africa, but that is the first big Third World problem we are aware of. But Canada, the UK and the United States all looked at their records from before 1982 trying to find evidence of this organism earlier and there is some scattered evidence of a few cases here and there, but we are quite confident that it was not a major public health problem before that time.

Senator CRAIG. Dr. Archer, you mentioned the role you are playing, the work you have done as it relates to retail food protection programs, and your desire to cooperate with USDA in this effort. It is important that we move forward quickly to gain as much knowledge as we can. We are concerned about the costs involved and possible duplication of effort. Are you aware of duplicate efforts between FDA and USDA?

Dr. ARCHER. No. Possibly, I could think of one or two——

Senator CRAIG. Your Retail Food Protection Program is something quite separate and apart from anything the USDA is currently doing?

Dr. ARCHER [continuing]. Yes, Senator.

Senator CRAIG. I don't have any further questions. Thank you both very much, gentlemen.

Senator DASCHLE. Thank you, Senator Craig.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. I am really struck by the fact that this is an emerging disease, possible unknown before 1982. Will we be seeing more of this or other kinds of diseases like this in the future?

Dr. BLAKE. That is possible, and that is one of the points that is made by this report from the Institute of Medicine. Things are changing. For example, the distribution of a large proportion of our food is now controlled by just a few companies, and you can have very rapid dispersal of contaminated food from just one source.

For example, a few years ago there were a quarter million cases of salmonellosis in the Chicago area caused by milk that was improperly pasteurized—a very rapid dispersal of food. There are differences in the way animals are being raised. Rather than having a few chickens in the backyard, you have tens of thousands of chickens together. There are the pressures of antibiotics on organisms both in humans and animals. Roughly half of the anti-microbials produced are used in animals and they put pressure on organisms to change.

There are organisms that emerge because people are changing, AIDS, for example. There are people who are much more susceptible to organisms which previously didn't seem to cause much of a problem. There is the problem of anti-microbial-resistant tuberculosis, for example. We thought a number of years back that we were on the verge of being free of infectious diseases, that it was no

longer a problem in the developed world. We are finding, to our chagrin, that they are very much with us and a continuing threat. We have to be careful to maintain our resources and be on our guard to combat these diseases as they come along.

Senator MURRAY. Is it safe to say that standards we set in place in 1950 and 1960 may no longer apply?

Dr. BLAKE. That is probably out of my province.

Senator MURRAY. Well, I will ask Dr. Archer. I am pleased to see that you have increased your recommendation to 155 degrees. I am concerned that it is only a recommendation rather than a binding regulation. I am concerned by previous testimony indicating that even in Washington State where the requirement is 155 degrees, it may not be implemented at fast food restaurants.

A recommendation—what does that mean? Does that mean that I can count on going into a restaurant and knowing that there is an enforceable Federal requirement in effect?

Mr. ARCHER. It is a recommendation and a standard that we propose to the States that their State legislatures adopt, codify, and then can enforce.

Senator MURRAY. So the States enforce it. You recommend it to the States and they enforce it?

Dr. ARCHER. It is up to the States to enforce, yes.

Senator MURRAY. OK. In the case of Washington State—this may be out of your jurisdiction—where it is 155, how does that information get to the restaurants and how could a restaurant not know that?

Dr. ARCHER. That I can't answer. I am sorry.

Senator MURRAY. That question bothers me. Even beyond that, I'm concerned about the implementation of it altogether and I'm concerned that if this is an increasing incidence, that we will see more cases and we have to look at higher temperatures and better safeguards in the restaurants themselves. Just having a recommendation doesn't mean that I am assured as a consumer of protection against things like *E. coli.*

I am also very concerned about who in the restaurant is implementing temperature requirements. If it is a 16-year-old standing in a fast food restaurant with a couple of friends, am I assured that temperature requirements are going to be implemented? We need to address these concerns.

Dr. ARCHER. Senator, if I could comment on the 155 recommendation, we feel very strongly that cooking is not the total solution to this problem. We struggled internally with the decision to raise the temperature for the following reason. We could raise it to 165 and afford more assurance, or 175. There is the issue of consumer acceptance and palatability.

There is also the chance that by raising the temperature, you run the risk of someone thinking: Well, we don't have to worry if the beef or fish or whatever is out at room temperature too long because we are going to cook it to 175. There are a lot of public health considerations that you need to factor in.

Raw-animal-derived products can be cross-contaminated—properly cooked but contaminated after the fact. There are other things that we factor in before we make shifts of that type.

Senator MURRAY. Again, I'm concerned that it is only a recommendation and not implemented as a binding requirement. I understand it is only part of a larger problem; that we need to look at all phases of the beef coming in and where it is being cooked, but it is a concern I have. Thank you.

Senator DASCHLE. Thank you, Senator Murray. Dr. Blake or Dr. Archer, one last question before we take up the last panel. We talked about the higher incidences of *E. coli* traced to northern locations. Is there also a relationship between higher incidences of *E. coli* in certain kinds of cattle?

Dr. BLAKE. I don't know.

Senator DASCHLE. Dr. Archer.

Dr. BLAKE. I am sorry. Yes, there appears to be a higher incidence in dairy cattle. I thought you were asking about breed—and why it would be in dairy cattle, I am not sure, but over and over again the problem seems to be traced back to dairy cattle. As you know, dairy cattle, once they stop producing an adequate amount of milk, are eaten and they are relatively lean, so that in producing hamburgers, as I understand it, they would mix dairy cattle, which is largely lean, with fat to get the appropriate fat content. But we do not know why dairy cattle are more affected than other types of cows.

Senator DASCHLE. Well, we thank you both for your expertise and the information you have shared with us. I had hoped to bring our witnesses back. I know the time is running quickly and we almost are at that point when I had hoped the hearing would have concluded, but I thank you very much for coming and we will determine after the last panel, I suppose, whether or not we will have time to bring everyone back. I prefer to do that at this subcommittee, but perhaps time will not allow that today. We thank you both.

Our final panel is comprised of Mr. James Marsden, the Vice President for Science and Technical Affairs of the American Meat Institute; Dr. John Marcy, Assistant Professor of Food and Science Technology, Virginia Polytechnic Institute and State University; and, finally, Ms. Carol Tucker Foreman of Foreman and Heidepriem, testifying on behalf of the Safe Food Coalition.

Mr. Marsden, we are pleased that you could be with us and since I called your name first, let us begin with your statement.

STATEMENT OF JAMES L. MARSDEN, VICE PRESIDENT FOR SCIENCE AND TECHNICAL AFFAIRS, AMERICAN MEAT INSTITUTE, ARLINGTON, VA

Mr. MARSDEN. Thank you, Mr. Chairman. My name is Dr. James Marsden. I am Vice President of Scientific and Technical Affairs for the American Meat Institute. We express our deepest sympathy for the families that have been affected by this outbreak. The AMI and I personally are saddened and troubled by this, and we pledge our full support to USDA, FDA and the other regulatory agencies involved as we look for a solution and look to make sure it doesn't ever happen again.

This outbreak is even more tragic because it could have been avoided. We know that cooking controls this organism. We know that there are a lot of other issues that need to be addressed. Since

this is an emerging pathogen—it has only been known to affect human beings since 1982—there is a lot that we don't know. Much research will be needed before we can fully understand it.

However, research, while valuable, takes time and can only provide answers and help correct problems in the long term. Consumers and the food industry want answers now. The encouraging news is that we have some of those answers for preventing future outbreaks and it is the short-term solutions that I would like to focus on today.

We know that the pathogen responsible for this outbreak, *E. coli* 0157:H7, is highly heat-sensitive and is eliminated through proper cooking. We know that State and Federal hamburger cooking guidelines have been woefully inconsistent. We know that neither everyone in the food service industry nor every consumer is aware of the need to cook ground beef thoroughly, and we know that there is a dire need for more information about this organism and safe food handling in general by consumers, the news media, industry and State and local governments.

For the past five years, AMI has conducted research on this organism and in 1989 AMI issued an interim guideline to assure the microbiological safety of pre-cooked meat patties. [2] It addresses processing requirements for pre-cooked patties which assure that *E. coli* 0157:H7 and other pathogens are destroyed. The guidelines specifically call for a minimum cooking temperature of 155 degrees.

Since these guidelines were implemented in 1989, no pre-cooked beef patties have been implicated in foodborne outbreaks of *E. coli* 0157:H7. I stress that in dealing with this emerging pathogen the only proven point of prevention is the cooking process.

In the recent outbreak, the Washington State Health Department had implemented this same 155-degree cooking temperature requirement for fast-food hamburgers. Apparently it was not widely communicated to restaurants in the State and the targeted temperature at Jack In The Box restaurants was well below the 155 degrees.

It is ironic that this outbreak would occur in the State of Washington, the only State in the United States with such a high hamburger cooking requirement. All other States require hamburgers to be cooked to 140 degrees, a temperature far too low to kill this strain of bacteria.

As an interim step, FDA has just revised the model food code cooking provisions for ground beef and recommends it be cooked to at least 155 degrees. The previous FDA model food code recommended a minimum internal temperature of 140 degrees, again far too low. USDA also recommends a minimum cooking temperature of 155 degrees for restaurants and is recommending that consumers cook ground beef to 160 degrees, building in an extra margin of safety for home cooking.

As this outbreak is fully investigated, more facts regarding the undercooking of the ground beef will emerge. USDA's investigation shows that the outbreak would have been avoided if the ground beef patties had been cooked to 155 degrees. As proper cooking in-

[2] See page 97.

formation is communicated and acted on, the possibility of another outbreak is greatly reduced.

The recommendation for thorough cooking, while serving as a proven and immediate prevention method, is not enough to avert a similar tragedy in the future. We know little about the origin of this microorganism and how it is transmitted. Research is desperately needed. Therefore, we have called for a USDA–FDA joint task force to initiate, expedite and oversee research on *E. coli* 0157:H7, investigating all points in the food production chain from animal agriculture to food handling and cooking where the organism can be eliminated.

I emphasize the importance of approaching this problem holistically, looking at the entire food production, processing, distribution and handling system. Changes in one segment of the food production continuum will not prevent problems further upstream or downstream and cannot be viewed as a panacea for preventing foodborne illnesses.

Even if perishable foods such as meat and poultry were to arrive at food service establishments in a completely sterile form, they could still be contaminated through improper food handling practices and cause further outbreaks of foodborne disease. Even if FSIS greatly increased its existing microbiological sampling program, random sampling cannot find every pathogen in the entire supply of raw meat and poultry, nor does microbiological testing or monitoring serve as a preventative activity.

In short, it is myopic to focus only on one segment of the food production continuum as a stop-gap for foodborne illness. All segments of the food chain must dedicate themselves to preventing future problems, and the meat and poultry industry is an important segment. In fact, it is the only segment which is held to Federal inspection requirements.

With respect to the Federal meat inspection program and its role in assuring the safety of meat and poultry products, it has long been recognized that the system needs to be modernized and directed more to controlling microbiological hazards. In 1985, the National Academy of Sciences outlined several characteristics of an optimal meat and poultry inspection program. One of the NAS recommendations was that USDA's Food Safety and Inspection Service place a greater emphasis on the Hazard Analysis and Critical Control Point system (HACCP), focusing its inspection attention and resources on the risk most important to public health and safety.

Properly used, HACCP provides an effective tool to produce product in compliance with regulatory standards and significantly decreases the risk of foodborne illness. Traditional inspection programs tend to focus on detection and response to problems rather than on relying on properly designed prevention programs. Managing critical control points in the production processes assures a safe end product and requires only monitoring by inspection personnel. Microbiological testing is useful to verify that the HACCP system is working properly.

In evaluating a process control approach versus a microbiological standards approach using microbiological testing to establish, accept or reject criteria, it is useful to examine how FDA and the dairy industry assure the microbiological safety of milk.

Raw milk, as well as raw meat, can be a reservoir for *E. coli* 0157:H7 and other pathogens. One way to further protect the public from pathogens would be to establish microbiological standards for raw milk and then set out to test all loads of milk, holding the product until the test results prove the absence of pathogens. This would be enormously costly to Government, the dairy industry, and to consumers, and in the end there would still be no absolute assurance that consumers would be protected from microbiological hazards.

The process control approach which was implemented and has worked so well involves the establishment of a critical control point, in this case heat pasteurization, which destroys pathogens in raw milk. Microbiological testing is used to verify that the pasteurization critical control point is working properly. The consumer still plays a role in the overall safety of milk by following safe handling practices, but the consumer or the food handler in a commercial establishment has a wider margin of safety because of the earlier critical control point.

When heat pasteurization was introduced for milk almost a century ago, it wasn't called HACCP, but that is exactly what it was. A similar approach from farm to table can also work for meat and poultry products. The success of a HACCP program depends on the underlying research that identifies critical control points in the process and provides controlled procedures to determine if standards are met. FSIS has adopted HACCP in principle, but has yet to recognize the concept in a general regulatory framework. AMI believes these programs, if more widely adopted, will significantly improve the meat and poultry inspection program.

Finally, turning again to the importance of research to help us surmount technological obstacles and eliminate *E. coli* 0157:H7, AMI is researching the use of gamma radiation to control this pathogen. Preliminary work done at USDA's Agricultural Research Service suggests that irradiation can successfully control *E. coli* 0157:H7. Our research will establish the dose of irradiation required to kill this organism and other microbiological pathogens, and evaluate the consumer acceptability of ground beef that has been pasteurized using gamma irradiation. A copy of the AMI irradiation research project is included in my prepared material. [3]

In summary, Mr. Chairman, everyone in the food chain, including the ultimate consumer, plays an important role in food safety protection. Most foodborne illnesses stem from product abuse after manufacturing. All of the efforts made by the industry and government inspection services can be negated if food distributors, retailers, food service or consumers improperly store and handle meat and poultry products.

AMI believes Federal agencies should strengthen not only their research capabilities, but also improve their educational efforts to make food handlers and users more aware of their responsibility to protect the food they distribute or consume. Together, we can assure the safety of meat and poultry products.

That concludes my remarks, Mr. Chairman.

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[3] See page 113.

[The prepared statement of Mr. Marsden follows:]

PREPARED STATEMENT OF JAMES L. MARSDEN, VICE PRESIDENT FOR SCIENCE AND TECHNICAL AFFAIRS, AMERICAN MEAT INSTITUTE, ARLINGTON, VA

My name is Dr. James L. Marsden, Vice President of Scientific and Technical Affairs for the American Meat Institute (AMI). AMI is the national trade association representing packers and processors of meat and other animal protein products. Our members slaughter and process more than 90 percent of the meat products and half of the turkey products produced in the United States. AMI appreciates this opportunity to share our views on the Federal Food Safety Program and Government regulation of coliform bacteria.

Mr. Chairman, the American Meat Institute is deeply saddened by the recent foodborne illness outbreak associated with undercooked hamburger in the Northwest. We believe that this tragedy could have been avoided and we pledge our full support as USDA, FDA and other Government agencies act to identify and eliminate the cause of the outbreak.

The truth is, there is much we do not know about the pathogen responsible for this terrible outbreak in the Northwest, and much research is needed before we will be able to understand it. But research—while valuable—takes time, and can only provide answers and help correct problems in the long term.

Consumers and the food industry want answers *now.* The encouraging news is that we have some of those answers for preventing future outbreaks, and it is the short-term solutions I wish to focus upon today.

IMMEDIATE PREVENTION RECOMMENDATIONS

We know that the pathogen responsible for the outbreak, *E. coli* 0157:H7, is highly heat sensitive and is eliminated simply through proper cooking. We know that State and Federal hamburger cooking guidelines have been woefully inconsistent. We know that not everyone in the food service industry nor every consumer is aware of the need to cook ground beef thoroughly and we know that there is a dire need for more information about this organism and safe food handling in general by consumers, the news media, industry and State and local governments.

For the past five years, AMI has conducted research on *Escherichia coli* 0157:H7. In 1989, AMI issued an interim guideline to assure the microbiological safety of pre-cooked meat patties. This voluntary guideline addresses processing requirements for pre-cooked patties which assure that *E. coli* 0157:H7 and other pathogens are destroyed. The guidelines specifically call for a minimum cooking temperature of 155 degrees Fahrenheit using precisely calculated combinations of time and temperature. Since AMI's guidelines were implemented in 1989, no pre-cooked beef patties have been implicated in foodborne outbreaks of *E. coli* 0157:H7.

I would stress here that in dealing with this emerging pathogen, the only point of prevention currently documented, proven and available in the food chain is the *cooking process.*

AMI has called on the Secretaries of both Agriculture and Health and Human Services to immediately adopt the AMI guideline as the Federal standard for cooked hamburger. We are also calling on all State health departments to adopt the AMI guideline immediately, and we are distributing copies of our guideline throughout the food industry. This action will help to address the inconsistent requirements nationwide, as well as the need for information about controlling this pathogen.

In the recent outbreak, the Washington State Health Department had implemented the same 155 degrees Fahrenheit cooking temperature requirement for fast food hamburgers. However, the requirement was apparently not widely communicated to restaurants in the State—and the targeted temperature at Jack-In-The-Box restaurants was well below 155 degrees.

It is ironic that this outbreak would occur in Washington State, which we understand is the only State in the Union with such a high hamburger cooking requirement. All other States require hamburgers to be cooked to 140 degrees, a temperature which is far too low to kill this strain of bacteria.

As an interim step, we understand that FDA has just revised the model food code cooking provisions for ground beef and is recommending that ground beef products should be cooked to heat all parts of the food to at least 68.3 degrees Celsius (155 degrees Fahrenheit). The previous FDA model food code recommended a minimum internal temperature of 140 degrees Fahrenheit—again, far too low.

USDA is also recommending a minimum cooking temperature of 155 degrees for restaurants and is recommending that consumers cook ground beef to 160 degrees, building in an extra margin of safety for home cooking.

As this outbreak is fully investigated, more facts regarding the undercooking of the ground beef will fall into place. However, based on USDA's investigation, it is clear that the outbreak would have been avoided if the ground beef patties had been cooked to 155 degrees. As proper cooking information is communicated and acted on, the possibility of another outbreak is greatly reduced.

AMI recognizes that the recommendation for thorough cooking—while serving as a proven and immediate prevention method—is not enough to ensure that a similar tragedy does not occur in the future. We know little about the origin of this microorganism and how it is transmitted and research is desperately needed. Therefore, we have also called for a USDA/FDA joint task force to initiate, expedite and oversee research on *E. coli* 0157:H7, investigating all points in the food production chain from animal agriculture to food handling and cooking, where the organism can be eliminated.

FOOD SAFETY IS A SHARED RESPONSIBILITY

I want to emphasize the importance of approaching this problem holistically, looking at the entire food production, processing, distribution and handling system. Changes in one segment of the food production continuum will not prevent problems further upstream nor downstream, and cannot be viewed as a panacea for preventing foodborne illness.

Even if perishable foods, such as meat and poultry, were to arrive at food service establishments in sterile form, they could still be contaminated through improper food handling and cause further outbreaks of foodborne disease.

Even if FSIS greatly increased its existing microbiological sampling program, random testing cannot find every pathogen in the entire supply of raw meat and poultry, nor does microbial testing or monitoring serve as a preventive activity.

Even if some new technology were approved to eliminate pathogens from raw meat—such as irradiation, which is approved for use in poultry—there would be no guarantee that pathogens could not be reintroduced to that product in the retail store, food service establishment or home, resulting in foodborne illness.

In short, it is myopic to focus only on one segment of the food production continuum as a stopgap for foodborne illness.

THE ROLE OF MEAT AND POULTRY INSPECTION

But all segments of the food chain must dedicate themselves to preventing future problems, and the meat and poultry industry is an important segment. In fact, it is the *only* segment which is held to Federal inspection requirements. To help evaluate and if necessary modify those requirements, we have also urged Secretary Espy to convene a meeting of the National Advisory Committee on the Microbiological Criteria for Foods. This committee's collective expertise will be invaluable as scientists seek ways to reduce exposure to this pathogen.

With respect to the Federal meat inspection program and its role in assuring the safety of meat and poultry products, it has long been recognized that the system needs to be modernized and directed more to controlling microbiological hazards.

In 1985, the National Academy of Sciences (NAS) outlined several characteristics of an optimal meat and poultry inspection program. One of the NAS recommendations was that USDA's Food Safety and Inspection Service place a greater emphasis on the Hazard Analysis and Critical Control Point System (HACCP), focusing its inspection attention and resources on the risks most important to public health and safety.

The NAS report devoted considerable attention to improved control of microbiological and chemical contaminants. These potential health hazards provide unique challenges to USDA and the regulated industry. Microbial and chemical contaminants do not lend themselves to the traditional inspection procedures that rely on physical inspection by sight, smell and touch. Advanced diagnostic technologies must now be used to make decisions important to public health and safety.

Even though sophisticated detection methods are currently available, in many cases they are too time consuming to allow normal movement of products through the marketplace. The microbiological test for *E. coli* 0157:H7, for example, requires six days to confirm a positive sample.

Consequently, the industry has increasingly relied on preventative control programs based on sound science and a management commitment to build safety into each critical step of the process. These programs, commonly called Hazard Analysis Critical Control Points or HACCP, have become the watchword for process control.

THE ROLE OF PROCESS CONTROL, OR HACCP

Properly used, HACCP provides an effective tool to produce product in compliance with regulatory standards and significantly greater safety assurance to consumers than exists under current inspection programs. Traditional inspection programs tend to focus on detection and response to problems rather than relying on properly designed prevention programs. Control of critical points in the production process assures a safe end product and requires only monitoring by inspection personnel.

Microbiological testing provides a useful role in verifying that the HACCP system is operating properly. In evaluating a process control approach versus a microbiological standards approach (using microbiological testing to establish accept/reject criteria), it is useful to examine how FDA and the dairy industry assure the microbiological safety of milk.

We know that raw milk can be a reservoir for *E. coli* 0157:H7 and other pathogens. One way to attempt to protect the public from pathogens would be to establish microbiological standards for raw milk and then set out to test all loads of raw milk, holding the product until the test results prove the absence of pathogens. This approach would be enormously costly to Government, the dairy industry and to consumers and in the end, there would still be no absolute assurance that consumers would be protected from microbiological hazards.

The process control approach which was implemented and has worked so well, involves the establishment of a critical control point—in this case heat pasteurization—which destroys pathogens in raw milk. Microbiological testing is used to verify that the pasteurization critical control point is working properly. The consumer still plays a role in the overall safety of milk by following safe handling practices, but the consumer or the food handler in a commercial establishment has a wider margin of safety because of the critical control point that occurs earlier in the process.

When pasteurization was introduced for milk almost a century ago, it wasn't called HACCP but that is exactly what it was.

A similar approach applied from farm to table can also work for meat and poultry products. The success of a HACCP program depends on the underlying research that identifies critical points in the process and provides control procedures to determine if standards are met. FSIS has adopted HACCP in principle but has yet to recognize the concept in a general regulatory framework. AMI believes these programs, if more widely adopted, will significantly improve the meat and poultry inspection program.

Clearly, controlling microbiological contamination of meat and poultry products is a primary concern for USDA and the regulated industry. However, even under optimum conditions, bacteria will be present in the food chain. We know that microbiological contaminants can enter processing plants in or on livestock, from the air and from humans. New technology developed in part by AMI research on organic acid carcass sprays and decontamination procedures offers practical means to reduce microbial contaminants. USDA's recent approval of pre-evisceration organic acid sprays for beef carcasses can reduce the level of coliform bacteria as well as *Listeria* monocytogenes and other pathogens. Research is currently underway to evaluate the effect of organic acids and tri-sodium phosphate on *E. coli* 0157:H7.

Despite industry's best efforts to minimize microbiological contamination, contrary to prevailing public understanding, technical experts familiar with the science of food microbiology know that the complete absence of microorganisms from raw food products, including meat, poultry, seafood and produce, is unrealistic and unattainable. Moreover, public safety is not served by the complete elimination of microorganisms from food.

In fact, many microorganisms are beneficial and an absolutely sterile food supply is not a desirable objective. The food manufacturers' objective is to maintain pathogenic microorganisms at levels that don't pose a risk to human health.

The task of defining microbiological criteria for known pathogens is very complex. Nevertheless, USDA and FDA should be commended for undertaking this arduous task through the formation of an expert panel on microbiological criteria. These efforts along with additional epidemiological and analytical research can provide the basis for more effective food safety regulation.

AMI RESEARCH AND EDUCATION

Turning again to the importance of research to help us surmount technological obstacles and eliminate *E. coli* 0157:H7, I would like to report that AMI is also conducting research on the use of gamma radiation to control this pathogen. Preliminary work done at USDA's Agriculture Research Service suggests that irradiation

can successfully control *E. coli* 0157:H. Our research will establish the dose of irradiation required to kill the organism and evaluate the consumer acceptability of ground beef that has been pasteurized using gamma radiation. A copy of the AMI irradiation research project is included with my statement. After this month, AMI will hold a one-day seminar to educate all segments of the meat and poultry food service and retail industries on cooking methods to kill this pathogen.

CONCLUSION

Finally, I would like to underscore that everyone in the food chain, including the ultimate consumer, plays an important role in food safety protection. Most foodborne illnesses stem from product abuse after manufacturing. All of the efforts made by the industry and Government inspection can be negated if food distributors, retailers, food service or consumers improperly store and handle meat and poultry products. AMI believes Federal agencies should strengthen not only their research capabilities but also improve their educational efforts to make food handlers and users more aware of their responsibility to protect the food they distribute or consume. Together we can assure the safety of meat and poultry product.

Mr. Chairman, this concludes my remarks. I will be happy to entertain the committee's questions.

Senator DASCHLE. Thank you, Dr. Marsden.

Dr. Marcy.

STATEMENT OF JOHN A. MARCY, ASSISTANT PROFESSOR OF FOOD SCIENCE AND TECHNOLOGY, VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY, BLACKSBURG, VA, ON BEHALF OF THE INSTITUTE OF FOOD TECHNOLOGISTS, CHICAGO, IL

Mr. MARCY. Thank you for inviting me, Mr. Chairman. I feel obligated to reiterate several things today. Food from animal origin may never be totally free of pathogenic bacteria. Sampling to detect pathogens will not eliminate a hazard.

The best scientific approach to assure food safety is the HACCP system. That is what you indicated you wanted me to address, among other things, and that cannot be said enough. Proper cooking or heat treatment will always be a critical control point to eliminate pathogens.

On a day-to-day basis, food safety is not a scientific problem or a regulatory problem. It is a management opportunity and obligation. Everyone says that the problems are at the preparation stage. We have the science today for the most part to prevent and eliminate that occurring with cooking. It is a management problem at that step.

Government cannot——

Senator DASCHLE. I shouldn't interrupt——

Mr. MARCY [continuing]. That is quite all right.

Senator DASCHLE [continuing]. But you both have mentioned this and it is an interesting point. I recall for purposes of the record that our previous witnesses said that it isn't just a matter of heat. Maybe you could address that. They said that it is a matter of both heat as well as time, and that combination of heat and time produces the confidence that we have killed the bacteria, the pathogen. Do you both agree that it is a combination of heat and time even though you haven't mentioned time?

Mr. MARCY. Yes.

Mr. MARSDEN. Yes, sir. For example, in AMI's guidelines for precooked patties, there are two ways to achieve the appropriate ther-

mal process. One is to achieve an instantaneous temperature of 155 degrees or a minimum of 155 degrees. You can also target a lower temperature if you hold the product at that temperature for some prescribed period of time. There is a heat lethality curve that exists for *E. coli* 0157:H7 and you can look on that curve at various temperatures up and down the temperature range at what necessary time is required for holding. So, indeed, it is a time-temperature relationship.

Senator DASCHLE. I was sure that you agreed with the prior witnesses, but I think that because you both made references only to heat I thought it was important and call that to your attention. Dr. Marcy, do you agree?

Mr. MARCY. Most assuredly, bacteria definitely are destroyed on a time-temperature relationship. As Dr. Archer pointed out, in order to get rare roast beef we can cook at 130 degrees for 120-some minutes, whatever that relationship is, and there would be opportunities in determining proper times and temperatures with *E. coli*—we don't know what those are—particularly the 0157:H7 strain.

Once that time-temperature relationship is known, the key to prevention is to strive for continuous improvement in the food supply. There is no reason to stop now. We can improve. The key to control is a management opportunity, an obligation, at the food service level or even in the household.

Government at the Federal, State and local level should not and cannot be the controlling force in food safety. Most foodborne illness outbreaks result from a combination of bacterial growth and human error.

We have regulations, we have requirements, we have laws. That doesn't prevent human error, nor are inspectors there to control the actions of the cook or the foodhandler. The only sure way to control is with a HACCP system, to control through the process. HACCP dictates that you follow the process. You scientifically evaluate the hazards, you apply those monitoring procedures to verify that the process is in control, and if it is not in control you stop, take corrective action, document what you have done, learn from that and move on.

It is a flexible system subject to constant improvement, but it cannot be driven by regulation alone—the ownership of the HACCP plan must be in the hands of the people that control the process—the producer, the processor, the distributor, the food service operator, the management, the homemaker, whoever is doing the cooking, even if it is the kids.

We have talked today about legislation, regulation. The key—and it has been said before—is education. We have a wealth of knowledge within the Beltway and without. There are ongoing educational programs in HACCP, and have been for years—the program with the Educational Foundation of the National Restaurant Association, the Food Marketing Institute, AMI, the National Broiler Council, and others. Through that education—until we get every manager and every employee of every restaurant thinking, "today I am going to fix the food safely, we will make the progress to solve the problem. They must think safety with every action they take.

Now, what will drive that process? Should it be mandated? I don't think so, because in order to have ownership they have to develop it. We can, from a regulatory standpoint, provide the information they need, evaluate their plans, help them, educate them. But they have to put in place whatever it is that will control it for them. They have to have the ownership, the buy-in. Then it will work from the top executives on down. Hopefully they are all thinking after this, there but for the grace of God go I. Mr. Nugent said he wished he knew.

HACCP is proactive. You can go out and seek that information about hazards, but we should ask ourselves, well, why didn't Mr. Nugent know. We have a wealth of knowledge that we haven't communicated to other people, but the key to control is in the process, not regulation.

Thank you.

[The prepared statement of Mr. Marcy follows:]

PREPARED STATEMENT OF JOHN A. MARCY, ASSISTANT PROFESSOR OF FOOD SCIENCE AND TECHNOLOGY, VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY, BLACKSBURG, VA, ON BEHALF OF THE INSTITUTE OF FOOD TECHNOLOGISTS, CHICAGO, IL

Millions of servings of meat and poultry are prepared daily with proper handling and cooking thus creating a food that is both nutritious and safe. Our confidence is literally shattered, however, when something that we eat causes illness to us or our families. We EXPECT every meal and food that we eat to be beneficial, nutritional excesses aside, and certainly not immediately harmful. With the information that we have today, it is completely within our reach, as a society, to accommodate that expectation better than we do now, but how we do that is open to debate and is the basis for this statement.

Raw foods of animal origin have never been, are not now, nor are they likely to be in the future, 100 percent safe for human consumption. Animals that produce the products that we eat are living creatures that are subject to exposure to microorganisms found readily in the environment and/or in animal or human populations. Humans and animals depend on microorganisms for many positive things, such as digestion of food and decomposition of waste, fermentations of food products and production of medicines. However, a small percentage of the spectrum of microorganisms are capable of causing illness in either humans or animal or both.

The National Research Council identified in its report on the scientific basis of meat and poultry inspection 11 genera of microorganism as containing species that are both pathogenic and transmissible to humans by **ingestion of raw or undercooked** meat (N.R.C., 1985). This list contained:

Bacillus antracis
Balantidium coli
Campylobacter coli
Campylobacter fetus subsp. *fetus*
Campylobacter jejuni
Escherichia coli
Francisella tularensis
Salmonella
Sarcocystis spp.
Taenia saginata
Taenia solium
Toxoplasma gondii
Trichinella spiralis
Yersinia enterocolitica
Yersinia pseudotuberculosis

All of these organisms, plus others, can be transmitted to humans through **ingestion of cooked or otherwise heat-processed** meat or poultry that becomes contaminated after the heat processing or that is improperly stored after the initial heat processing (N.R.C., 1985). It should be readily apparent that proper heat treatment and proper handling after heating are **the most critical points** in the process from farm to consumption in order to prevent any of these microorganisms from causing illness.

The coliform group of bacteria are defined as short, gram-negative rods that are capable of producing acid and gas from lactose in 48 hours at 37 °C. As a group, the coliforms have been used for many years as an indicator of the possible presence of harmful enteric pathogens, such as *Salmonella. Escherichia coli (E. coli)* is one of the bacteria included in this group. The organism that would become known as *E.*

coli was first described by Dr. Theodor Escherich in 1885 (Doyle and Padhye, 1989). As the predominant bacterium of the microbial flora normally found in the intestinal tracts of warm-blooded animals, it is logical to use *E. coli* as an indicator of possible fecal contamination. The species was generally considered nonpathogenic until 1945, when Bray (1945) reported on the association of serologically homogeneous *E. coli* in children with severe diarrhea (Doyle and Padhye, 1989).

With the documentation that *E. coli* had pathogenic strains, it became increasingly important to develop testing procedures that would be more sensitive, or specific for *E. coli*. The fecal coliform test was developed to limit the detection of those members of the coliform group that were not part of the normal intestinal flora. Other tests for *E. coli* incorporate the chemical 4-methylumbelliferone glucuronide to provide a fluorogenic product of *E. coli* metabolism. Neither of these common tests for detection of *E. coli* will in fact detect *E. coli* 0157:H7. Tests for specific determination of *E. coli* 0157:H7 have been developed, but can take three days or more.

Bacterial cells and spores are easily spread from the hide/skin of the live animal to meat surfaces and work surfaces during the slaughter/evisceration process. Even with the utmost care, low levels of bacteria are transferred to the meat. The temperature of the product must be reduced as quickly as possible to prevent the bacteria on the meat surfaces from multiplying. In the production of ground beef, the bacteria are distributed throughout the product. At this point, the only process to kill the vegetative bacterial cells is cooking the meat. If the meat is not consumed right away, it must be handled in a proper manner to prevent recontamination or bacterial spores from germinating and becoming a source of foodborne illness.

The Hazard Analysis Critical Control Point (HACCP) system is a methodology to critically evaluate all points of the food production/processing system for individual products. HACCP as a food safety management system has been adopted by many national and international food companies as well as Federal and State regulatory agencies. The principles and application of HACCP for food safety has been endorsed by organizations such as the Codex Alimentarius Commission, the World Health Organization, the International Commission on Microbiological Specifications for Foods, the National Academy of Sciences, and the USDA/HHS/DOD/DOC National Advisory Committee on Microbiological Criteria for Foods (Pierson, 1992).

Under HACCP hygienic practices during slaughter and evisceration are observed and evaluated to minimize bacterial contamination. Carcass sprays and washes may be utilized to decrease the bacterial load present prior to cooling. The time necessary to cool the carcass is monitored to assure the process is in control and to note deviations and make corrections. Sanitation and product temperature control are critical control points during the boning, trimming, grinding, mixing, forming, freezing, and packaging operations. However, these control points will only prevent multiplication or reduce the level of inherent contamination present, they will not assure elimination of bacterial pathogens.

Microbial analysis is often used in the verification step of a HACCP system, but seldom used as a control because of the length of time required to obtain results. In order to be effective, immediate feedback is required to alter or stop a process that is not in control. When a process deviation occurs at a critical control point, corrective action must be taken and the product produced from the last time the process was known to be in control till the process deviation is noted should be retained and handled according to dispositions predetermined in the written HACCP plan.

It should be clear that any bacterial specie that comes to the processing facility on or in the live animal can conceivably be an inherent contaminant of the meat from that animal. A functioning HACCP plan should evaluate the process that produces the animal for market to determine if there are any critical control points that may be used to eliminate, prevent or reduce hazards to an acceptable level. The system can be effectively used to prevent drug residues by careful monitoring of withdrawal times, but no methods have been developed that would eliminate enteric pathogens in general or *E. coli* 0157:H7 specifically from the live animal. Because of the uniqueness of *E. coli* 0157:H7, it may be possible in the future to screen animals prior to slaughter to determine presence/absence of this particular organism and determine appropriate control measures for the meat from those animals.

The HACCP system must also consider the distribution of the product, the intended use, and the people that will consume the product, with particular attention to "at risk" groups such as infants, elderly, or immunocompromised. A meat processor will not usually have control over these process points, but must evaluate the hazards nevertheless. The normal assumption is that raw meat will be properly handled and properly cooked prior to consumption. In most cases, this is a valid assumption as evidenced by the numbers of portions that are served without illness.

However, it is clear that not all raw meat and poultry are properly handled and cooked prior to consumption. One of the topics before this subcommittee is to evaluate the possibility of screening raw meat and poultry for pathogenic bacteria prior to distribution. Bacterial screening for specific pathogens on or in raw meat does not necessarily eliminate the hazard. Because meat and meat products do not usually have the homogeneity required to make assumptions about the lot from sampling, no sampling plan can give complete assurance that all portions are free of pathogens, even if the sample is negative. Therefore, the hazard is not eliminated and proper cooking is still the critical control point that assures elimination of the hazard. In fact, HACCP was developed because sampling can never give 100 percent assurance of safety, and it is essential to:

(1) Identify all possible hazards;
(2) Determine the correct process to eliminate the hazard;
(3) Decide how to monitor the process to identify when the process was not in proper control; and
(4) Plan for corrective action in a non-crisis situation.

I have been asked to address HACCP specifically and how to enhance it to improve the safety of the food supply. As stated previously, HACCP must consider the entire chain of processes from production to consumption, even though there is usually no single entity that is in control of every step of that chain, especially as it relates to meat and poultry products. The cooking process is the critical control point that must receive the focus, irrespective of whether it is the largest meat processor, a foodservice establishment, or the household cook that performs the operation. The buck stops here.

How can HACCP be applied in this diverse setting? In the foodservice industry, employees can be important factors in prevention and control of illness, both as potential mishandlers of foods and direct sources of contamination (Harrington, 1992). This is an important concept throughout the food processing/preparation process. The 1992 National Food Safety Workshop; sponsored by the Cooperative Extension Services of Arkansas, California, Indiana, Maryland, Texas, and Virginia; workshop participants from governmental agencies, industry, and academia, identified education as the best, most effective solution to most food safety problems. The lack of the specific knowledge or skills to adequately handle and prepare food is the most readily addressable approach with the largest return on investment of resources. Many States have been offering food safety education through Cooperative Extension, health departments, community colleges, high schools, et cetera, for several years. Both FSIS and FDA have information readily available for distribution through many means. Trade associations such as the Educational Foundation of the National Restaurant Association, the Food Marketing Institute, American Meat Institute, and others have instituted HACCP training for several years.

During the Food Safety Workshop, James Denton, Head, Department of Poultry Science at the University of Arkansas and chairman of the National Educational Forum on Food Safety Issues listed several keys to successful food safety improvement:

(1) Based on *sound* scientific information, i.e., HACCP-based Quality Assurance (QA) systems as a component of Total Quality Management (TQM);
(2) Integrate TQM from production through the marketing chain to the consumer—an *education process;*
(3) Realize that honest differences of opinion exist; however, there must be *consistent messages,* not conflicting information which is presented in a self-serving manner;
(4) Regulatory function, like QA in the food industry, cannot become inflexible—it must be allowed to adapt as our knowledge base changes.

HACCP also puts the responsibility and the accountability for food safety in the hands of the groups that can control the process; the producer, the processor, the distributor, the retailer, and ultimately the consumer. The role of the regulator is one of compliance verification and system evaluation. To use an adage of process control, "You cannot inspect quality into a product, it must be built in." The same applies to safety, particularly with regard to bacterial control, prevention, and elimination.

I would encourage the subcommittee to:

- Accept the Hazard Analysis Critical Control Point (HACCP) system as the most appropriate, science-based management tool to assure food safety;
- Encourage adoption of HACCP throughout the food production to table chain;
- Accept that proper cooking and handling are critical control points regardless of who performs the operations;

• Evaluate the merits of education as one part of the HACCP process that can be accomplished, in large part, with resources presently available.

Thank you for the opportunity to speak with you today.

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JOHN A. MARCY, ASSISTANT PROFESSOR, EXTENSION SPECIALIST, POULTRY PROCESSING FOOD SCIENCE AND TECHNOLOGY

John A. Marcy received his M.S. and Ph.D. in Food Technology from Iowa State University and his B.S. in Food Technology and Science from the University of Tennessee. Dr. Marcy worked for Stokely-Van Camp for six months as an undergraduate and began work in the poultry industry in 1975, working for Swift & Co. and Jerome Foods in the areas of quality assurance and production management. He spent seven years in industry before returning to graduate school. After leaving Iowa State, Dr. Marcy was Director of Quality Control for Portion-Trol Foods, a USDA Total Quality Control facility supplying meat products to the foodservice industry. Dr. Marcy joined the faculty of Virginia Tech in August of 1988. Dr. Marcy's research interests are meat microbiology and food safety. He has published eight research articles since 1984. Dr. Marcy is a member of Phi Kappa Phi, Gamma Sigma Delta, Sigma Xi, Mu Sigma Rho, Alpha Zeta, The Institute of Food Technologists, and the International Association of Milk, Food, and Environmental Sanitarians. He was an instructor of statistical quality control for the American Meat Institute for four years. He has been active in training Cooperative Extension Home Economists in Virginia to teach Foodservice Sanitation to the foodservice industry and participated with the Educational Foundation of the National Restaurant Association in the development of their HACCP-based recertification course, "Managing A Food Safety System".

Senator Daschle. Thank you, Dr. Marcy.

Ms. Foreman.

STATEMENT OF CAROL TUCKER FOREMAN, FOREMAN AND HEIDEPRIEM, WASHINGTON, DC, ON BEHALF OF THE SAFE FOOD COALITION

Ms. Foreman. Thank you, Mr. Chairman. I am here today representing members of the Safe Food Coalition and I have listed those members supporting my testimony, if you would put that in the record, please.

Senator Daschle. Without objection.

Ms. Foreman. The first thing that the groups asked me to do was to express their appreciation for Secretary Espy's very active involvement and his very vigorous response to the outbreak of *E. coli* 0157:H7 in Washington State. We think it is extremely impor-

tant for people to know that their government officials care. Caring enough to fly all the way across the country to appear at a hearing is a good way to start his tenure at USDA. We regret that the beginning of his tenure coincided with this tragedy, but we thought his response was very impressive.

We appreciate, too, the Senate Agriculture Committee holding this hearing to examine the details of what happened. Although we are grateful for the Secretary's involvement, I have to say that the Department of Agriculture's response evokes a certain sense of déjà vu for those of us who have been dealing with this for a long time.

There is a pattern. Every time there is a very serious foodborne illness outbreak, there is a flurry of activity. The Department issues some new plans and some new programs. The television covers it for a few days and then it disappears and everybody seems to go back to business as usual.

I think we all understand that we have a food poisoning problem in this country. Some kinds of foodborne illness are increasing very substantially. There are about 6.5 million cases a year of foodborne illness; about 9,000 people die from it. I agree with the other witnesses that virtually all of us have a responsibility in preventing food poisoning—those of us who cook the food, whether it be in a home kitchen or a restaurant; local, State and Federal governments; as well as the people who produce the animals and process the food.

Today I direct my remarks particularly to the Department of Agriculture's food inspection system because it spends $500 million a year of the taxpayer's money to inspect meat and poultry, and because the Department of Agriculture stamps every package of meat and poultry with a symbol that says "inspected for wholesomeness, United States Department of Agriculture."

The meat and poultry inspection system is mired in the past. It does not put people and their health first. It is oriented more to animal health than to human health. That is its history and that is where it remains. The inspection system is not based on science. It relies on sight and smell and feel, but you can't see or feel or smell harmful bacteria. According to the National Academy of Sciences (NAS), the meat and poultry inspection staff at USDA views the regulated industry as its peer group and its constituency.

The USDA inspectors mark all meat and poultry products with a stamp that says "inspected for wholesomeness," but that is just a formality. They don't really mean it. Dr. Cross earlier this week told the Washington State Senate, and I quote, "Raw meat contaminated with harmful bacteria is safe." [4] I am not sure by what miracle of science that happens and I think we have been saying here today that it is not the case. It is a peculiar interpretation of an old court ruling, and Dr. Cross asserts that the meat may make you sick, but under the law it is safe.

I have attached to my statement two legal opinions, one from David Vladeck, counsel for Public Citizen, and the other from Daniel Marcus, a former general counsel of the Department of Ag-

[4] See page 121.

riculture. [5] They agree that this interpretation of the law is, to put it bluntly, hogwash. However, if the Department can't be moved from that view, then the next question is why not come to Congress and ask you to change that law. The decision USDA cites was written in 1974. Since I served after that, I have to put myself among those who failed to ask you to change the law.

If you were to go back to your States and tell the voters that raw meat and poultry that are contaminated with bacteria are, in fact, safe, you would rejuvenate the term limitation movement.

I have some suggestions for change. First, since we can't assure that raw meat and poultry aren't contaminated with harmful bacteria, why not stop putting the seal on them? We could replace it with instructions for safe food handling. It would help to get the word out. I was very pleased that Secretary Espy has food handling instructions on packages as part of his proposal to you. It doesn't have to be a dire warning. It can be very straightforward language, the same kind of language that USDA uses in the educational material that it puts out in printed form and on television.

Second, it would be a good idea to move to a public health agency the responsibility for setting standards for what constitutes contamination in raw meat and poultry. We are talking about what makes human beings sick. It strikes me that that is a public health issue and one that might be explored more successfully in an agency that is staffed by public health experts.

USDA has an inherent conflict of interest in this area, and Congress is responsible for that. You told the Department of Agriculture to promote the production and sale of meat and poultry and other agricultural products, but you told them in another law to protect the public health. Sometimes those things conflict and it causes a tension at USDA that has not been handled positively. USDA officials tend to get confused about what comes first. There shouldn't be any confusion. Public health should come first.

Secretary Espy brought you a new plan for a lot of changes in meat and poultry inspection today. As he noted during his testimony, he didn't do that without first checking that plan out with the industry. He did not meet with consumers. He did not meet with public health officials. But, before he brought that plan up, he met with representatives of the regulated industry. USDA developed the plan with representatives of the industry. I don't believe that in other regulatory agencies in the Government in Washington that that would happen on a continuing basis. At USDA, it does.

We all agree that we desperately need a science-based meat and poultry inspection system. I, like everybody else here today, endorse the HACCP system. We need science, but we have got to know whose science we are going to use. USDA tends to rely very heavily on studies done by the regulated industry. Sometimes those studies have not been peer-reviewed or published in peer-reviewed journals before they are used by USDA to change the regulatory procedures. I don't know any other agency in Government where that would be done.

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[5] See page 125 for Vladeck, page 129 for Marcus.

In 1985, the National Academy of Sciences laid out specifically what was needed in order to develop that science base. USDA has simply not implemented the National Academy of Sciences' suggestions. In a management report issued by the Department last year on the Food Safety and Inspection Service, USDA acknowledged that FSIS had begun to take action on fewer than 20 percent of the recommendations in the NAS report.

Secretary Espy said today that the Department believes that rapid on-line tests are a good thing to have to help detect bacterial contamination in meat and poultry. Obviously, if you had an on-line test, you wouldn't have to retain the product and cost the producer money.

In 1985, the NAS in its report pointed out to USDA that other people had recognized the value of those on-line tests as early as 1974, and said USDA should have made more progress in this direction by then. It is now 1993, and today the Department says, hey, we are going to start developing on-line tests. If FSIS had started in 1974, my guess is you would have something that works very well and probably by now would not be very expensive. If we had started then, we would be there now and you wouldn't have to ask would microbial tests require detaining the product and costing money, would that be a several-billion-dollar-a-year activity to test all of that product. I think we would have cheap and easy tests, and be a lot further along the line to preventing these kinds of outbreaks than we are.

We have conquered a lot of very difficult scientific problems in this country over the last 20 years. We have taken calculators and computers from being luxury items to being cheap things that everybody owns. We have almost conquered childhood leukemia. But with regard to the inspection of meat and poultry by the Federal Government, we are just about exactly where we stood in 1906.This indicates that change is not a very high priority and that change directed primarily to protecting the public health is not a very high priority.

Finally, throughout the testimony today there have been references to *E. coli* 0157:H7 being a very rare form of food poisoning. It is a fairly new form of food poisoning, but there is a substantial number of studies written about other outbreaks of this particular strain of *E. coli* since 1987—Minnesota, Utah, Nebraska, and obviously Washington State. This is a problem that has popped up a number of times, and it is only now getting the attention it deserves.

Thank you very much.

[The prepared statement of Ms. Foreman follows:]

PREPARED STATEMENT OF CAROL TUCKER FOREMAN,[6] FOREMAN AND HEIDEPRIEM, WASHINGTON, DC, ON BEHALF OF THE SAFE FOOD COALITION

Mr. Chairman, I am Carol Tucker Foreman. I appear today on behalf of the following members of the Safe Food Coalition: [7] Consumer Federation of America, Center for Science in the Public Interest, National Consumers League, Public Citizen, Government Accountability Project, United Food and Commercial Workers International Union, and the Food and Allied Service Trades Department of the AFL–CIO. In addition, Consumers Union joins in support of this statement. Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* with approximately 5 million paid circulation, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

All of the groups that I represent today have asked that I express our appreciation to Secretary of Agriculture Mike Espy for becoming actively involved in addressing the outbreak of *E. coli* 0157:H7, for demonstrating his concern by crossing the country twice in one day to meet with the victims' families and health officials in Washington, and for stating that he will do everything he can to assure that there are no more tragedies like this one. In Olympia the Secretary committed his Department to doing a better job. We have sought exactly that response for years. A Secretary who cares is the first step in making the process work better.

We believe Secretary Espy faces serious challenges in making the Nation's meat and poultry inspection system work adequately.

Food poisoning is serious and some of the most serious types are increasing. Researchers at the Centers for Disease Control estimate that there are about 6.5 million cases of foodborne illness each year in the United States and about 9,000 deaths (CAST Task Force Report). Most of the cases can be traced to meat, poultry, eggs and shellfish. We may have the world's safest food supply, but it clearly isn't safe enough.

Some of the increase in food poisoning appears to be an outgrowth of major changes in our population, food processing system and consumer habits. The prevailing meat and poultry inspection laws were passed in the late 1960's. The world has changed a lot since then. We have high speed, mass production food processing. There is some evidence that this contributes to contamination. We transport more food across the country and import more from other countries.

In 1993, few women stay home and spend hours preparing food. Consumers eat on the run. We buy from carryouts. We cook in microwave ovens. We eat at fast food chains. More and more of our food is bought partially prepared. Furthermore, Americans are different than we were a quarter of a century ago. In 1967 the baby boom was just ending. Today, the early boomers are facing 50. We are an aging population. The fastest growing segment of our society is over the age of 80. In the future, we are more likely to live with chronic illnesses that increase our susceptibility to food poisoning.

The meat and poultry inspection system, the laws governing it and the Department administering it have not kept up. The meat and poultry inspection system is static and mired in the past. In 1993 it still depends on the same basic approach that was instituted in the first meat inspection law passed in 1906. Inspectors look, sniff, and feel, but they cannot see, smell, or touch pathogenic bacteria or harmful chemical residues. They check for diseases that make animals sick but don't affect humans. They inspect for aesthetic problems—hair, feathers, bruises—that make a product unappetizing, but not unhealthful.

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[6] Carol Tucker Foreman is a partner in the Washington, DC public policy consulting firm, Foreman & Heidepriem. From 1977–81, she served as Assistant Secretary of Agriculture for Food and Consumer Services. Her responsibilities included direction of the Nation's meat and poultry inspection programs. She is a member of the Council on Agricultural Science and Technology (CAST) Task Force on "Risks Associated With Foodborne Pathogens" which will issue a report on its work in the spring of 1993.

[7] The Safe Food Coalition, an alliance of consumer advocacy, senior citizen, whistleblower protection and labor organizations was formed in 1987 to work for improvements in the Nation's food inspection programs.

FSIS regulations require that the agency approve all floor plans before a meat or poultry plant can open. If major changes are made, the agency must review and approve them. FSIS regulations prescribe the height of the risers on staircases in packing plants and the size of the type on labels. The agency specifies how many feet there must be between a drinking fountain and a sink used for handwashing. It cannot, however, tell you or me what constitutes an infective dose of *Salmonella* or determine what the *Salmonella* count on a piece of chicken is before the chicken has been packaged, transported, sold and eaten.

The Food Safety and Inspection Service does what it knows how to do and has always done, rather than change to meet new challenges. Ten years ago, FSIS contracted with the National Academy of Sciences to:

—examine the scientific basis of the Nation's meat and poultry programs;
—make a comprehensive analysis of different inspection strategies, including risk assessment, to predict their impact on human health; and
—make recommendations based on new developments in biological research and technology and in food science that might be used to make the programs more effective. [National Academy of Sciences, *Meat and Poultry Inspection: the Scientific Basis of the Nation's Program* (hereafter referred to as NAS), p. v.]

In 1985, the Academy issued its report and, couching fairly shocking news in very careful language said, "* * * the committee could not find clear evidence that the traditional inspection system and modifications to it * * * are based on objectives and criteria that relate to public health * * *. (NAS, p. 7)

The committee recommended that FSIS make major changes and base a new inspection system on scientific proof of the impact on human health of each of the procedures and requirements of the inspection system. It urged that FSIS develop "rapid diagnostic procedures for detecting microorganisms, especially species of *Salmonella* and *Campylobacter.*" (NAS, p. 4)

The committee also noted that the value of rapid testing methodologies had been recognized for more than a decade, but that *as of 1984* FSIS had only a few on-line tests. "The committee maintains that much more could have been done by now (1985)." (NAS, p. 161) As of the beginning of 1993, USDA has not developed and put into effect on-line tests for microbial contamination. On Monday of this week Dr. Cross said to the Washington State Senate, "Regrettably, there is no in-plant test developed and approved for microbiological testing of raw meat and poultry products. This is one of our highest priorities * * *."

Others recognized the need for these tests 20 years ago. NAS told FSIS to make them a priority 10 years ago. FSIS now has gotten around to doing so.

The committee also criticized the agency for not having an adequate system for testing for chemical residues in meat and poultry (NAS, p. 5). Eight years later, it still doesn't have one.

Last year a management review committee set up by Assistant Secretary Smith under directive of Secretary Madigan concluded that only about 20 percent of the NAS recommendations had been the subject of any action.

The failure to follow through on the NAS recommendations illustrates the very serious lack of leadership and creativity at the highest levels of FSIS management. This is also reflected in the agency's response to food poisoning episodes, including the Administrator's response to the *E. coli* 0157:H7 outbreak.

Despite the agency's failure to develop and adopt procedures that would have helped prevent the *E. coli* outbreak, the FSIS Administrator maintains that, if you get sick from eating contaminated meat or poultry, it is your fault.

In Seattle earlier this week, the Administrator testified that raw meat with pathogens is not considered adulterated. "Our review and investigation has shown that all of the meat implicated in this outbreak was inspected and met the Federal criteria for 'safe raw meat.' The bottom line is that raw meat contains bacteria, but proper cooking kills bacteria." (p. 2) There are several problems with his position.

First, it gives a new meaning to the old phrase *caveat emptor.* But he can see the label on the package that says "Inspected for wholesomeness, USDA." A reasonable person would assume that if it says wholesome it means just that. The label was put on the package by a USDA inspector. But, in a neat move the Administrator dodges any responsibility for the illnesses and deaths because the meat wasn't cooked thoroughly.

Second, in a January 22 memorandum to Secretary Espy, the Administrator cites a 1974 court decision, *APHA* v. *Butz,* 511 F.2d 331 (D.C. Cir. 1974). He said the court ruled that "the presence of bacteria in raw meat and poultry does not constitute adulteration under the authorizing legislation" and that "Congress did not intend the prescribed official inspection legends on meat and poultry products to import a finding that the products were free from salmonellae and other bacteria in that

Congress did not intend that inspections include 'microscopic examinations'." (Cross Memorandum to Sec. Espy, January 22, 1993.) [8]

Legal memoranda from two highly regarded experts in food safety law argue that the Administrator is just plain wrong. It is a convenient way to defend the Department's failure to reduce microbial contamination, but, if you read the decision, it doesn't say what the Administrator suggests. I would like to ask that legal memoranda from Daniel Marcus, partner in Wilmer, Cutler and Pickering and former General Counsel of the USDA and David Vladeck, counsel for Public Citizen be entered into record.

They both note that the court ruled USDA is not *required* to put warning labels on raw meat and poultry, but never suggested the agency is prohibited from doing so. Further, and more importantly, if the product is sufficiently contaminated to "ordinarily" threaten health, it is clearly adulterated. If USDA had developed the rapid on-line tests for this microbial pathogen and others, it might have determined that the product was in fact contaminated and been able to prevent the tragedies that occurred.

You've been told today that the law doesn't protect consumers. I think the legal memoranda show that is wrong. You've also been told that existing science can't protect consumers. Government and industry assert nothing can be done because we don't have good enough tests and it would take too long to get the results back. I'll tell you, Mr. Chairman that, in the 26 years since the Meat Inspection Act passed, we've sure dealt successfully with much more complicated scientific problems. We've sent people to the moon, developed micro computers, virtually beaten childhood leukemia. We haven't found ways to determine that meat is contaminated, not because it is too difficult, but because the people who run the system and the people who are regulated by it are too comfortable with the status quo. The public suffers as a result. We are spending a half billion dollars a year for a rickety, ineffectual system, bad science and poor leadership. The public deserves better.

There may also be a reason to question the commitment of some FSIS management to the agency's basic mission. People are shocked by this severe outbreak of *E. coli* 0157:H7, but USDA shouldn't be surprised. The Department has had other serious *E. coli* food poisoning outbreaks within the past few years. Last spring the Kansas City Star was awarded the Pulitzer Prize for a series on USDA. The series included articles on three major meat-related outbreaks of this and other strains of *E. coli*.

In the summer of 1987, a shipment of tainted beef killed four retarded patients at two Utah mental institutions. Fifty other residents and workers were taken to hospitals. USDA had inspected the meat. It also distributed it. And, despite the illnesses it caused, the Department refused to recall the meat and refused to test it for *E. coli*. Doctors found evidence of *E. coli* 0157:H7 in several of the victims.

In July 1990, at least 70 persons attending an agricultural threshing show in Hampden, ND became sick after eating rare roast beef contaminated with *E. coli*. Sixteen were hospitalized.

In October 1988, 32 junior high school students in Coon Rapids, Minnesota got sick with fever, chills and bloody diarrhea after the school cafeteria served them precooked, frozen hamburger patties. Once again, *E. coli* 0157:H7 was implicated.

Perhaps even more shocking than the frequency of problems associated with *E. coli* is the fact that the Star reported that the USDA official in charge of warning Americans of contaminated meat products declined in each of these cases to recall the contaminated meat because it would be burdensome to the producer and because the meat would not cause illness if cooked thoroughly. He also told the Star that he hates to penalize packing plants because, in his view, "There are no bad meat packers." (See the Kansas City Star, December 8–14, 1991.)

The NAS Committee report suggested that this attitude—an identification with the problems and concerns of the regulated industry instead of the public—is a serious problem at FSIS. I would add another factor, the revolving door. Top officials of FSIS regularly leave the agency to take high positions with regulated companies and trade associations. The last Administrator and one of his top deputies left FSIS and reappeared a few weeks later as vice presidents of the National Association of Food Processors and the Grocery Manufacturers Association, respectively.

Finally, Mr. Chairman, the USDA is confronted with a basic conflict-of-interest in administering food inspection programs. On the one hand, Congress has directed the USDA to promote the welfare of American farmers and promote the sale of agricultural products. On the other hand, Congress has directed USDA to administer a

[8] See page 133.

public health program. Sometimes the two are in direct conflict. If you speak plainly about the problems of contaminated food, you may make it less attractive and undermine sales. USDA has wrestled with this problem, but has not solved it. It is clear that the meat and poultry inspection system needs better, more up to date science and better, more creative managers. It may also need a change of venue. Meat and poultry inspection started as an animal health program. A changing environment requires that it become a public health program. In the long run, it may be better for the public and for USDA to have the program located in an agency whose first goal is human health.

If the decision is made to try to operate a meat and poultry inspection program from USDA, the Secretary should take the following steps:

—Bring new leadership to FSIS. The present Administrator is on an exchange program from Texas A&M. He should return to that position and be replaced by someone who brings an exceptionally strong record in development and administration of a public health program and a reputation for commitment to strong science. It might be a good idea, in addition, to recruit from the Pentagon or NASA a highly qualified systems engineer to help develop new inspection procedures and programs. Further, the agency needs to recruit a staff of public health experts to balance the existing staff that is heavily weighted to veterinarians and food technologists.

—Ask the NAS to pick up where it left off and develop a detailed research program on risk determination, rapid on-line microbial tests, microbial standards, and the other developments that the first NAS group recommended. NAS has some history in examining meat and poultry programs. It has the confidence of consumers and industry. It could help develop agreement on appropriate research projects. NAS has not demonstrated, because it was not requested to do so, that it understands the need for new regulatory methods for inspection. I think regulatory methods research is important and people with this expertise should be added to the NAS panel.

—Ask Congress to appropriate funds for FSIS to institute a competitive grants program to develop risk assessment data, on-line tests and regulatory methods needed to move to a science-based inspection program. FSIS presently depends on the Agricultural Research Service and the regulated industry for much of its data. The latter source is absolutely unacceptable. The ARS system has some fine scientists but FSIS has no power to direct their work so that it is shaped to look for the information necessary to be useful in a regulatory setting.

—Contract with NAS to work with the FSIS staff to develop the details of a HACCP system. The work done to date by FSIS is of very limited value because it is not based on a risk assessment, the essential first step in developing a workable HACCP program.

There are a multitude of other changes that should be made to open the agency and bring inspection into the last half of the twentieth century. The steps I have listed here would at least lay the groundwork for other necessary changes.

Senator DASCHLE. Thank you, Ms. Foreman. I am not ready to condemn Secretary Espy for all of the inaction of his predecessors, but I certainly hope to hold him and his entire Department accountable for a lot of what they have indicated today they intend to do.

What guidelines would you have for this subcommittee in making sure that we hold them accountable? What would you suggest as an appropriate set of criteria to judge their actions and their plans, as you have heard them today?

Ms. FOREMAN. That is a very good question and I hope that you will hold them accountable. I certainly did not intend to condemn Secretary Espy. A new Secretary of Agriculture inherits an ongoing bureaucracy. If he wants to survive and prosper, he had better deal with it early on.

I suggest that you first ask the Department to give you substantially more detail about what is involved in achieving each of the goals of the new program. Ask them to share that checklist with you, the priorities and the time line for each part.

I have some other suggestions in my prepared statement, including that they refer back to the 3 NAS reports. Those reports, particularly the 1985 report, which USDA asked for, contracted for, and paid for, are as good a primer on what should have been done as I have ever seen.

USDA should now go back to the NAS and ask it to update the 1985 report. A new study should include how to develop a research program that would help achieve the specific things NAS recommended in 1985; what kind of research projects should be undertaken to get rapid on-line serological tests; how to explore DNA probes to detect bacteria; how to explore microbial markers, benign microbial markers; and what process is best for achieving that program. Then it would be terrific if you in Congress would give the Food Safety and Inspection Service some authority for a competitive grant program that would enable the staff to go out and say to scientists around the country, this is what we need to do our regulatory business, bring us a proposal and we will fund research to carry it out. Then, you would really begin to see some progress.

Both Congress and USDA must have a specific list of what is involved in each of those steps, and a time line for it. And if you will share the proposal with me, I will tell you if it is realistic.

Senator DASCHLE. You indicated an understandable degree of skepticism about yet another grand plan for addressing some of these problems. As we pressed them for details, they indicated that they had hoped that on the first track, what they called an evolutionary track dealing with the current set of regulations and guidelines and inspection standards, they would come up with a range of changes that could take place anywhere from another month to two years, but the outside parameter for that first track was approximately two years. How realistic is that?

Ms. FOREMAN. I don't know. They didn't share their plan with me, and without sitting down and going through even the outline of what it is, I can't tell you if it is realistic or not.

Senator DASCHLE. Do you find any fault with the concept of a two-tiered system, a two-track system, one dealing with the current set of practices within the Department and another dealing with sort of a brainstorming approach whereby all concepts could be considered and implemented and hopefully considered carefully for future implementation?

Ms. FOREMAN. That is probably not a bad way to go. I am reluctant to endorse plans that get thrown together in the time between an outbreak of food poisoning and the time of a Senate hearing.

Senator DASCHLE. For the record—and I don't mean to defend Secretary Espy, but he has reminded us on several occasions now that he has only been on the job for approximately 15 days. So there may be something other than the outbreak that has generated this review of inspection and regulatory policies. Wouldn't you agree?

Ms. FOREMAN. I would. However, it wasn't shared with any of the people that I work with. If it has been under consideration by FSIS over an extended period of time, the agency never asked consumer leaders their views.

Senator DASCHLE. That is a fair criticism.

Ms. FOREMAN. One of the things I heard this morning was a reference to FSIS or USDA convening some major discussion group. It would be easier to achieve the goals if perhaps that were done by some third party where there was a feeling that the Chair was held by an unbiased third-party facilitator.

In order to build public confidence, and certainly that is a major issue here, this plan must be peer-reviewed, and it should be reviewed by a body like the National Academy of Sciences.

Senator DASCHLE. Thank you very much, Ms. Foreman. Let me ask Dr. Marcy and Dr. Marsden something that I asked Dr. Cross, and that is the degree to which we can learn from other systems. You both have indicated a high level of confidence in the HACCP system. I personally believe that HACCP has much to speak for it, but to what degree have you had the opportunity to examine foreign inspection and processing systems and taken what strengths from those systems we can and applied them to concepts used in the United States?

Mr. MARSDEN. I will go first if that is all right.

Mr. MARCY. That is fine.

Mr. MARSDEN. Around the world there are many opportunities for representatives not only of FSIS, but industry to work together with our counterparts, say, in New Zealand, Australia, Europe, and so on. This is very much an ongoing thing, and the whole issue of HACCP is not limited to what is happening here in the United States at FDA and USDA. It is going on all over the world in virtually every developed country that I know of. USDA is not operating in a vacuum. It is very much part of the scientific community as we move forward addressing food safety issues. I worked for a New Zealand company for several years, so I am very familiar with the meat industry in New Zealand. The things that we are implementing are consistent with what is happening in other parts of the world.

Probably the biggest difference between what we do here in the United States versus what is done in other parts of the world is our emphasis on animal disease. I agree with Ms. Foreman that we are probably overly focused on animal disease issues. When you look at public health risk, animal diseases would fall very low on that list. They have been very successfully addressed here in this country. Still, a very large percentage of the FSIS budget addresses those issues. That is probably not the case in other developed countries.

Another thing that other countries are looking at, and I suppose we are looking at here from a research perspective but not necessarily from a practical perspective, is immunological tests, serological tests, to determine whether or not an animal is diseased by some way other than visual inspection. That can be done with a blood sample or something along those lines. You lessen the need for the visual or organoleptic inspection that is done by inspectors.

Senator DASCHLE. Thank you, Dr. Marsden. Dr. Marcy, anything to add?

Mr. MARCY. I don't really have any basis for comparison with other countries with the inspection system. The HACCP approach to foodborne outbreak prevention is to look at the whole realm from the farm to the table and inspection is definitely part of trying to minimize contamination.

Ms. FOREMAN. Could I make two quick points?

Senator DASCHLE. Sure.

Ms. FOREMAN. One, HACCP is an international endeavor. The basic elements of a HACCP program were set out by the National Academy in a report, I think, in 1983. The first element of a HACCP system is risk assessment.

Risk assessment is a very formal scientific process that involves certain steps. USDA decided not to do those, and I will be very skeptical of their system until that is done. Dr. Cross, as Chair of the Microbiological Advisory Committee, has asked for a subcommittee chaired now by Dr. Archer to begin a risk assessment program. However, they started risk assessment three years after they had started the HACCP system. What management philosophy suggests that you begin with steps two, three and four, and then go back and try to take step one?

Senator DASCHLE. Dr. Cross emphasized a determination to create a scientific and risk-based system. He described what they are planning to do on at least two occasions as that, and so your skepticism is justified. One could ask why have we waited this long, why did it take something like this to generate it, but it appears that they have gotten the message.

Ms. FOREMAN. I think so, but, also, risk assessment is a very specific process for which there is acceptance of the steps across a variety of fields, and I do think they have moved to that now, but I haven't seen anything that shows that they have begun to put that into the regulatory process.

Senator DASCHLE. Well, help me establish the right questions, the right criteria by which we hold their feet to the fire.

Ms. FOREMAN. I would love to. Thank you.

Senator DASCHLE. I am determined to do that.

Senator Craig.

Senator CRAIG. Thank you, Mr. Chairman, and to all of the panel, let me thank you for your insight, your comments and your reactions. Jim, you mentioned critical control point. Could you broaden your explanation of that?

Mr. MARSDEN. Certainly. A critical control point is a point in the process where you can exercise some control over whether or not a pathogen is killed, for example, or minimized. To give you some examples, Secretary Espy mentioned organic acid sprays. That is a critical control point where you can exercise some control, not absolute control, but you can minimize the presence of pathogenic microorganisms. An absolute critical control point, for example, would be in the canning industry where a can is actually heat-sterilized, or in heat pasteurization of milk.

Senator CRAIG. Now, you tended to emphasize the cooking process as a critical control point. This part of food from farm or ranch through to consumer is really a three-part process of producing and processing and ultimately preparing and distributing. Are there critical control points throughout the process that should be observed?

Mr. MARSDEN. Sure. There are critical control points that go all the way back to the farm and throughout the system, but in the case of raw meat these are not absolute critical control points where you absolutely exercise control until you——

Senator CRAIG. You cannot gain absolute control?

Mr. MARSDEN [continuing]. Only when you get to the final critical control point, which is cooking. You can minimize and set up hurdles all along the food production chain so that you are going to have a lower probability that these pathogenic microorganisms will be present. But the only absolute critical control point that we have identified is the cooking process.

Senator CRAIG. Proper cooking is of immediate and paramount importance. Is that what you are suggesting?

Mr. MARSDEN. Yes, sir. Currently, it is the one critical control point that can absolutely eliminate this organism as a public health concern.

Senator CRAIG. Dr. Marcy, would you agree with that?

Mr. MARCY. Yes, but to take it further, the control has to be implemented by the people in control of the process.

Senator CRAIG. That was going to be my next question. I was a bit surprised for you to say that it can't be accomplished through Federal mandates. I thought we could do anything with a Federal mandate.

Mr. MARCY. Well, you can't get rid of *E. coli* and you are not there behind the chef when he is doing the cooking. There has to be motivation, there has to be ownership. I think that has to come from that side all through the food chain. Basically, food safety is good business, and that has to be realized.

Senator CRAIG. You are not suggesting that there should not be guidelines or reasonable standards to be met?

Mr. MARCY. Yes, but that is all part of the HACCP system. We have the knowledge to set minimums.

Senator CRAIG. The HACCP system is not a mandate, it is a process?

Mr. MARCY. Yes. It is a methodology to evaluate where hazards come into a process and to determine ahead of time how you will control them, monitor the control, then take corrective actions if you lose control. It is not written in stone, it is not written in law. It must be flexible, it must be verified, and it must be updated as part of a total quality philosophy to continuously improve. But for HACCP to work, the control has to be in the hands of the people controlling the process.

Jim said the same thing. A critical control point is a place where you can exercise control. Normally, foodborne outbreaks do not indicate a system failure. It is more often the individual, the actions of an individual on a given night. They made a mistake, they didn't think about the consequences. They may not have known the consequences.

We ask the food preparers to do a lot of things, but do they have the tools and the knowledge that they need to make the judgments before they take a shortcut? Most people will either live up to our expectations or live down to them.

Senator CRAIG. In other words, pilot error?

Mr. MARCY. Yes, but why? Were they given the right instructions?

Senator CRAIG. You are suggesting that HACCP outlines or provides a process by which you can't guarantee, but you can begin some level of assurance that the pilot, in this case, a grill chef——

Mr. MARCY. It is probably the only management tool that will guarantee food safety.

Senator CRAIG [continuing]. Absolutely?

Mr. MARCY. It has the best shot. It will work better than trying to regulate bacteria. We didn't engineer them and it is going to be awful hard to get rid of them. We cannot now and it is not likely that we will ever inspect out or regulate out any pathogen. As in building any quality product, you cannot "inspect in" quality. You can only build it in. That is part of the process.

Senator CRAIG. Ms. Foreman, do you agree with that?

Ms. FOREMAN. Not completely.

Senator CRAIG. Tell me why.

Ms. FOREMAN. First, HACCP is a process but it is not sufficient to be all of a regulatory scheme. If you to tell the American people that we have a Federal regulatory inspection program for meat and poultry, it can be HACCP-based, but it has to be something more than HACCP because I agree that HACCP is part of a process. A governmental regulatory scheme has additional elements. There must be penalties for violating the process and the public must be able to get access to information.

Perhaps we should do away with Federal regulation of meat and poultry. That is debatable. It is not acceptable to say the Federal Government is inspecting food and assuming its safety if there are no Federal standards or enforcement.

We should have standards for bacterial contamination. We have standards for time and temperature, and it should be possible to come up with standards for microbial contamination. Using risk assessment, it should be possible to say what is an infective dose of a particular pathogen, and build in a safety factor and an abuse factor from the point of origin to the point of consumption, to assure that you will not get to an infective dose for most people by this time. Those standards should be part of a HACCP system. There should be standards for contamination just as there are for time and temperature.

Once again, I am not suggesting that you tell people the product is sterile. I don't even think we should put on the product that it is "wholesome." Most people don't consider "wholesome" and "contaminated with bacteria" to mean the same thing. We should not mislead people.

Senator CRAIG. You mention in your testimony that Dr. Cross made a statement in Washington that you found unbelievable.

Ms. FOREMAN. Yes. He said that raw meat and poultry is safe. It can be contaminated with bacteria and be safe. I don't accept that and I don't think the public accepts it.

Senator CRAIG. You don't accept it if added to it were "if properly prepared before eating?"

Ms. FOREMAN. I don't accept the notion in a sentence and I don't believe that I misquoted Dr. Cross in my testimony. I think I used a full sentence.

Senator CRAIG. Well, we are going to ask that the record be held open so that we can find out the facts of that, because let me ask this question of you.

Ms. FOREMAN. I think I probably have it with me.

Senator CRAIG. Okay. Let me ask this question of you. You said that it would be a great device to remove us from office, and some of us look for devices for that purpose. Would I err to go back to my State of Idaho, where people have been infected by this bacteria, and say that a contaminated patty of hamburger, if cooked at 155 degrees for the appropriate time, is safe to eat?

Ms. FOREMAN. Would not be safe to eat?

Senator CRAIG. Or would be safe to eat if properly prepared.

Ms. FOREMAN. Absolutely.

Senator CRAIG. Now, you see, I have just said a contaminated patty of hamburger. You said in your statement, I believe, that a contaminated patty of hamburger would not be safe to eat.

Ms. FOREMAN. No. I misheard you. I thought I heard you say a patty of hamburger properly prepared.

Senator CRAIG. I did, a contaminated patty of hamburger properly prepared.

Ms. FOREMAN. But I didn't hear that word. I apologize. It would be a mistake for you to say that. I might change your sentence some to say: If it started out contaminated, it wouldn't be contaminated by the time it had been cooked.

Senator CRAIG. We had better be very careful about our semantics, then. Do you agree that there probably are hamburger patties on the market today that might have some *E. coli* in them but are being properly prepared and are safe?

Ms. FOREMAN. Absolutely, absolutely.

Senator CRAIG. All right.

Ms. FOREMAN. I object to suggestions from any Federal official, including you, that raw meat is safe even though it is contaminated. I think Dr. Cross made that comment because he was talking about under the law. I disagree with his interpretation of the law.

Senator CRAIG. I see.

Ms. FOREMAN. But it is an unwise thing to say.

Senator CRAIG. We have a better understanding now of what you meant in your earlier comments.

One other question of you, Ms. Foreman, that is a frustration to me. I read through your statement and you consistently quote a particular report from the National Academy of Sciences as to what they find and what they recommend. There is on page six of your testimony a paragraph in which you refer to the National Academy of Sciences committee report suggesting that a particular attitude exists inside USDA, and you cite FSIS, in particular, and then go on to talk about relationships and top officials as if to suggest that there might be collusion, a relationship that does not allow for the appropriate administration of the law.

In your lead sentence you go on and say, "* * * an identification with the problems and concerns," and so on.

Ms. FOREMAN. Would you tell me——

Senator CRAIG. Page six, fifth paragraph down.

Ms. FOREMAN. My pages are clearly different from yours.

Senator CRAIG. You go on to say that the National Academy of Sciences committee report suggests that this attitude, in referencing an attitude or relationship that was quoted that the Star reported: "* * * an identification with the problems and concerns of the regulated industry instead of the public * * * a serious prob-

lem at FSIS. I would add another factor," and you go on and talk about it. You have found it?

Ms. FOREMAN. Yes, thank you.

Senator CRAIG. When you reference the National Academy of Sciences report, in almost all other situations you leave the page number as to your reference. I noticed you did not there, and that made me curious because I would refer you to page 151 of the report where it says that, "The maximum use of producer and processor certification of product compliance with all critical regulations consistent with established good manufacturing practices in food processing and with adequate government oversight, an industry that is fundamentally responsible for its own compliance," and it goes on through the paragraph. It talks about the relationship in a positive way. You have spoken of it in a negative way. Could you explain why, because the same report that you quote——

Ms. FOREMAN. My recollection is that they, in fact, do, especially in the context of talking about the development of the HACCP system. In the context where I was quoting from, it was as the system has evolved over a period of time, there is a—I think they referred to it as a closed society where they viewed the industry as the peer group. I would be glad to get the citation and give you the page that it is on. [9] Maybe different people wrote the different chapters.

Senator CRAIG [continuing]. I was curious because it was inconsistent.

Ms. FOREMAN. I tried to be consistent, sir. It certainly reflects the view of the NAS report that the meat and poultry inspection agency is mired in the past. They were extraordinarily gentle in most of the language that they used to characterize it.

Senator CRAIG. I see. Thank you. Mr. Chairman, thank you. I have no further questions.

Senator DASCHLE. Thank you, Senator Craig. Ms. Foreman, Dr. Marsden, Dr. Marcy, thank you for your testimony and for your answers to all of our questions. We appreciate the help of all the witnesses today. We want to revisit this issue from time to time and apply the criteria that Ms. Foreman and others will be sharing with us to watch with great interest and obviously with great hope that we can succeed with the ambitious plans laid down by our Secretary this morning.

With that, the hearing stands adjourned.

[Whereupon, at 2:25 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

[9] See page 118.

APPENDIX

QUESTIONS SUBMITTED BY SENATOR LEAHY AND ANSWERS THERETO

Robert J. Nugent

Question 1. You are quoted in the New York Times, regarding this incident, as saying: "This is a catastrophe. It has become clear that we were not cooking our meat in compliance with Washington State standards." I have a report that says that tests revealed internal hamburger temperatures as low as 120 degrees but that Washington State requires temperatures of 155 degrees Fahrenheit. Did the New York Times quote you correctly?

Answer. Yes. At the time I made that statement, it had not come to my attention that our company had conducted its own internal cooking studies for all of 1992. Those cooking studies showed that the procedures that we had in place, and those that we had utilized since 1976, reflected substantial compliance with Washington State's requirements in that our test results showed an average internal cooking temperature of 154 degrees.

Question 2. A similar incident occurred in Washington State in 1986 in which two persons died, and many became ill. Why didn't you improve your cooking techniques then instead of waiting until now?

Answer. As you are aware, since 1976 up through early January, 1993, our cooking techniques were designed to insure compliance with Federal regulations. We understand that in 1986 the Federal government became aware of the incident you reference through investigative efforts conducted in part by people affiliated with CDC. CDC did not notify us, nor did any other Federal agency notify us, that the illnesses resulting from the Walla Walla Washington outbreak were based upon the retailer's failure to implement procedures which would insure a minimum internal cooking temperature of 155 degrees. In fact, until 1993, we were not notified by any agency that the Walla Walla outbreak resulted from a failure of the retailer to comply with any standards regarding internal cooking temperature. We now understand that the Walla Walla outbreak merely identified individuals who had contracted illnesses associated with *E. coli* 0157:H7. The outbreak implicated ground beef as a suspected or primary source of the infection but revealed no insight on a possible means of controlling the contamination.

Question 3. I understand that you have switched meat suppliers and that you no longer buy from Vons Companies. Are you conducting ongoing microbiological tests to make certain that the hamburger you are now buying is free of this form of *E. coli*?

Answer. We require our processors to take samples every 15 minutes during processing, and the finished product is held until test results for the presence of 0157:H7 are confirmed as negative. We believe that this program provides a high level of assurance that the ground beef is not contaminated with this bacteria.

Dr. H. R. Cross

Question 1. Much of the testimony being given here today stresses the need for greater consumer education in the preparation and handling of meat for the dinner table. What specific recommendations would you make regarding the slaughtering process to make sure an incident like this does not happen again?

Answer. Our pathogen reduction strategy focuses on: Pre-harvest production activities, rapid methods development, post-harvest activities, risk analysis, slaughter plant activities, processing plant activities, food service and retail activities, and consumer awareness.

Under slaughter plant activities, we recognize the opportunity to introduce useful microbial detection technologies into the present inspection program as they become

available. That is why several activities are based on current knowledge which suggests that pathogen presence on carcasses is likely associated with fecal contamination, that careful sanitation can reduce the potential for cross-contamination, that Hazard Analysis and Critical Control Point (HACCP) principles have high potential for benefits, and that more information about microbiological profiles for species and classes of animals brought to slaughter will provide better opportunities for fine-tuning interventions. These activities are as follows:

(1) Design and implement national microbiological monitoring programs for cows, poultry, and swine. A similar program is underway for steers and heifers. Data generated by the baseline studies will show an "average microbial profile" for the class of animal studied. A baseline study will be developed for ground beef, as well.

(2) Test "disabled" cows to determine the prevalence of fecal contamination as compared to normal cows to determine if disabled cows constitute a greater public health risk.

(3) Review and modify current slaughter procedures to reduce carcass contamination and prevent bacteria proliferation.

(4) Enhance veterinary coverage in plants that slaughter high risk animals.

(5) Strengthen requirements for maintaining records of purchase and sales transactions to facilitate identification and traceback of animals back to the farm.

(6) Develop and test a HACCP microbiological monitoring program for beef slaughter that targets critical control points identified as microbiologically important.

Question 2. Could random microbiological tests of meat and poultry have helped prevent the tainted meat from reaching the Jack In The Box restaurants?

Answer. We will never be able to test all product for every pathogenic microorganism. Even random testing would not necessarily have prevented the *E. coli* outbreak since testing one batch of meat or one carcass does not ensure the next batch or carcass is safe. The fact that we do not yet have a rapid test for *E. coli* that can be used in the plant environment makes it even more difficult to detect the microorganism.

We believe our best strategy is to focus on preventing contamination by focusing on critical control points in the production process. Microbiological testing will certainly have a place in the meat and poultry inspection program of the future; however, it will most likely be focused on critical control points in the production process rather than random tests of meat and poultry.

Question 3. Are their now plans underway for the Food Safety and Inspection Service to begin conducting random microbiological tests of meat and poultry?

Answer. As part of our pathogen reduction strategy, we plan to implement a microbiological monitoring program for beef slaughter and processing that targets critical control points identified as microbiologically important. This activity, which is based on the work of the National Advisory Committee on Microbiological Criteria for Foods, will lead to the implementation of HACCP sampling in targeted beef slaughter plants.

Question 4. If random testing isn't the answer, then how do we assure the public that meat they consume isn't tainted with lethal bacteria?

Answer. No matter how successful we are in reducing pathogens in meat and poultry, we will never be able to produce pathogen-free meat and poultry. Consumers will always need to handle and prepare meat and poultry safely. We must, however, assure the public we are doing everything possible to reduce pathogens to their lowest level possible. Our Pathogen Reduction Program is how we plan to meet this goal.

Dr. Paul Blake

Question 1. Many of the reported cases of this *E. coli* appear to be in Northern States. Why is that the case and what is the suspected mechanism that transmits this bacteria to cattle?

Answer. Reports of human *E. coli* 0157:H7 infection are more common in the Northern and Northwestern United States than in the Southern United States. More cases are reported from Canada than from the United States, and from western Canada than from eastern Canada. The reason for the "northern tier" phenomenon is unknown, but it appears to reflect a true higher number of cases rather than simply increased reporting. Some possible explanations are that there are regional differences (1) in carriage rates for *E. coli* 0157:H7 in cattle, (2) in the source of ground beef (dairy or beef cattle, perhaps with different carriage rates for *E. coli* 0157:H7), (3) in the type of slaughter methods used, (4) in the frequency with which people eat ground beef, or (5) in how well people cook ground beef.

The route by which cattle acquire *E. coli* 0157:H7 is unknown, and requires further study. They appear to acquire it at a young age; the highest isolation rates have been reported from post-weaned heifers, not from cows that supply meat for ground beef.

Question 2. How do we reduce the incidence of this pathogen in cattle?

Answer. To reduce the incidence of this pathogen in cattle, studies are needed to determine how it is acquired by individual animals, and how and why it persists in individual animals and in herds. From the answers to these investigations, we should be able to devise the appropriate prevention and control methods, such as changing farm practices or vaccinating animals.

Question 3. The New York Times has reported that there are approximately 6,000 cases of *E. coli* 0157:H7 reported each year. This number strikes me as very high considering that many of these cases are likely to go unreported. Are confirmed cases of this strain of *E. coli* routinely reported to the Centers on Disease Control and did the New York Times report that correctly?

Answer. Cases of *E. coli* 0157:H7 infection are required to be reported in fewer than half the States and are not reported to CDC. Many States are in the process of making this infection reportable, and CDC is proposing to make it reportable to CDC. However, even if culture-confirmed cases are reported, this would represent only a small proportion of the true number of infections because few clinical laboratories culture diarrheal stools for this pathogen. Therefore, most of these infections are probably never recognized.

From the little information available, the estimate of 6,000 cases of *E. coli* 0157:H7 each year in the United States does not seem too high. This corresponds to an isolation rate of 2.4 per 100,000 persons. This is less than half the isolation rate reported from Canada in 1987. It is also much lower than the isolation rate of 8 per 100,000 reported from a Seattle HMO in 1985–86. Almost all of the strains reported from that study were from persons with bloody diarrhea, and other studies have indicated that only about one-third to one-half of persons with *E. coli* 0157:H7 infection have bloody diarrhea, suggesting that the true rate of *E. coli* 0157:H7 infection in those Seattle HMO subscribers was higher.

Question 4. Are tainted food products or meat the primary source of these *E. coli* 0157:H7 outbreaks?

Answer. The available evidence indicates that ground beef is responsible for more outbreaks and sporadic cases of *E. coli* 0157:H7 infection than any other food product. However, CDC investigations are continually detecting additional routes of infection, including drinking raw milk, fresh-pressed apple cider, or unchlorinated municipal water, eating rare roast beef, and swimming in contaminated lake water. To better determine the magnitude of these infections and the responsible vehicles, clinical laboratories need to routinely culture diarrheal stools for this organism and to report isolations to health departments. Improved surveillance of *E. coli* 0157:H7 by health departments and streamlined reporting to CDC would lead to better detection of outbreaks. Well-designed epidemiologic studies of outbreaks and sporadic cases are needed to identify unrecognized vehicles of transmission and to determine the which food products are the most important sources of these infections.

Dr. Douglas Archer

Question 1. Dr. Archer, you have testified before this Committee regarding food safety several years ago. I understand that FDA issued a model food code guideline for the internal temperature for hamburgers of 140 degrees. I also understand that temperature has now been changed by FDA. What is the current best advice of FDA for the cooking of hamburgers?

Answer. The FDA, under authority of the Public Health Service Act, provides guidance to State and local food regulatory agencies. Much of this guidance is in the form of model codes. Our 1976 model Food Service Sanitation Code recommended that "potentially hazardous food," a category that includes hamburger along with many other foods, be cooked so that all parts of the food reach 140 degrees Fahrenheit.

In 1988, FDA issued a proposal to update and combine its various codes into one document. At that time, based on improved scientific data, we proposed to increase the cooking temperature for all "potentially hazardous foods" to 145 degrees Fahrenheit. The agency received thousands of comments on its proposal and is now finalizing the new Food Code.

On January 28, 1993, in response to the serious outbreak of illnesses and four deaths caused by the bacterium *Escherichia coli* 0157:H7 in Washington, Idaho, Nevada and California, FDA issued an interim guidance, based on data developed

under a USDA contract. This interim guidance includes the recommendation that hamburgers reach an internal temperature of 155 degrees Fahrenheit.

FDA's interim guidance will be superseded by the issuance, later this year, of the new Food Code.

Question 2. Organic acid rinsing of beef carcasses has been shown in industry studies to limit certain pathogenic bacteria such as *Salmonella* and *Listeria.* Would organic acid rinsing also limit *E. coli* bacteria and would this technique help prevent disease outbreaks caused by *E. coli* 0157:H7?

Answer. FDA would support any processing step which is both safe for consumers of the food product and effective in reducing the population of pathogenic bacteria on it. Regarding organic acid treatment specifically, the current data appear to be inconclusive as far as its efficacy for controlling *E. coli* 0157:H7.

MR. JAMES MARSDEN

Question 1. Do you know how many packing plants or slaughterhouses that are now practicing the organic acid rinsing of beef and how those procedures are working?

Answer. AMI's petition to USDA to allow the industry to use organic acid rinses to reduce microbial contamination finally received approval on November 21, 1992. To date, nine beef slaughter plants use this technology and five additional plants have ordered equipment and are in the process of securing USDA-approved facility control programs supporting the use of organic acid rinses.

This technology is effective in reducing bacteria on beef carcasses. Total numbers of bacteria, Coliform bacteria, *E. coli, Salmonella, Listeria* monocytogenes and *Staphylococcus aureus* are all substantially reduced when organic acid rinses are applied during the slaughter process.

AMI recognizes, however, that the organic acid rinse represents only one control point in the process and will not completely eliminate harmful bacteria. Our research strategy includes the identification of other control points, so that a series of hurdles are introduced into the process from farm to table that reduce the numbers of harmful bacteria in raw meat and poultry products below levels that pose a potential health risk.

Question 2. Do you agree with Sec. Espy's suggestions for improvements in meat processing and slaughtering?

Answer. AMI generally supports the overall pathogen reduction strategy that was outlined by Secretary Espy. We hope to have an opportunity to fully review the details of the strategy as they become available. Only after a complete review can we fully endorse the program.

Question 3. Some parents and some restaurants are simply not going to cook hamburgers thoroughly enough. Does AMI support any microbiological standards for raw meats?

Answer. While AMI agrees with your statement that some parents and some restaurants are simply not going to cook hamburgers thoroughly enough, we still believe that food handlers and consumers are an important checkpoint for food safety. To be an effective checkpoint, both consumers and food handlers need to understand how to handle food safely.

We believe education is part of the equation to reduce foodborne illness. In fact, we have partnered with the Food Marketing Institute, the National Live Stock and Meat Board, USDA's Food Safety and Inspection Service and HHS's Food and Drug Administration to create new consumer and food handler guides for safe handling and cooking of ground meat and ground poultry products. Copies of these are included for your information. We hope that these and other educational initiatives will help consumers and food handlers to better understand the need for thorough cooking.

AMI supports the use of microbiological testing as a means of verifying that safe food production processes at Critical Control Points are being carried out. These are the "CCP's" in a HACCP process. However, microbiological standards for raw meats are not practical, nor would they serve to protect the public health in the absence of a safe food process capable of reducing or eliminating harmful pathogens.

As an analogy, imagine if the dairy industry was regulated using microbiological standards for raw milk in lieu of pasteurization. Raw milk contains bacteria, and sometimes contains harmful pathogens. Heat pasteurization provides the safe food process that makes milk safe and convenient for consumers. Even if the product is mishandled, the process is forgiving enough to prevent mishandling. In relation to foodborne illness, microbiological standards cannot replace a safe food process. How-

ever, microbiological testing (e.g., to verify that the heat pasteurization process is working properly), provides an important component of the HACCP process.

DR. JOHN MARCY

Question 1. What specific procedures do you recommend for controlling the incidence of *E. coli* 0157:H7 on raw meats intended for human consumption?

Answer. Procedures that reduce bacterial contamination *in general* may also reduce *E. coli* 0157:H7 concurrently. Prevention of milk and fecal contamination of the carcass duing udder and hide removal should substantially decrease the likelihood of *E. coli* 0157:H7 contamination or lessen the bacterial load present due to unpreventable bacterial transfer. I would endorse the National Advisory Committee for Microbiological Criteria of Foods as one of the best references available. It has spent much time contemplating and discussing the scientific merit of all aspects of bacterial contamination reduction as it relates to meat processing.

It is not possible to guarantee the elimination of this or any other pathogen with the processing science available today. Even with microbial testing, it is not possible to confirm absence of the organism.

Careful comparison must be given to the relative value of an incremental change in the safety of the raw meat supply and the cost of this change and consideration of the subsequent effect upon availability of meat and poultry to that segment of the population that is both undernourished and economically disadvantaged.

Question 2. Would you support the irradiation of raw meats to reduce the incidence of *E. coli* 0157:H7?

Answer. I am supportive of *approval* to irradiate all meat, not just chicken, for the eradication of foodborne pathogens. However, I could not support a mandatory directive for irradiation, nor applying irradiation strictly to control *E. coli* 0157:H7. However, other vegetative pathogenic bacteria are also reduced by irradiation. I would urge the committee to promote the acceptance of irradiation as a safe and effective food process.

There is a distinct advantage of irradiation of poultry that may not be the case with ground beef. It is much more likely that an individual piece of poultry will have pathogenic bacteria on the surface of the product than ground beef. This serves as a vector for the bacteria into the food preparation environment and increases the possibility of cross-contamination of non-cooked or pre-cooked items. However, poultry is not usually undercooked and therefore poultry that is consumed shortly after cooking is very safe and not likely to cause foodborne illness. With ground beef, the consumer may wish the ground meat to be prepared rare or medium rare and an insufficient thermal process of time/temperature may result. If this thermal process coincides with a higher level of contamination than normal, foodborne illness may result.

MS. CAROL TUCKER FOREMAN

Question 1. What can USDA line inspectors do to protect the public against lethal pathogens in meat since these pathogens are not visible to the naked eye?

Answer. Fourteen FSIS inspectors recently wrote to Secretary Espy suggesting changes in the inspection system, which could be made now, and which would make the present system work better while FSIS develops and tests a new science-based system. Those changes show how inspectors can do their job more effectively until a new system is in place. The Safe Food Coalition has endorsed these changes, pending implementation of a more modern system.

PREMISES FOR GENUINE REFORM

I. Program Integrity: There must be a fully-trained and staffed inspection force with the freedom to detect and consistently enforce the food safety laws on the books, without obstruction due to politics reflected by informal appeals and secret law.

II. Budget control: There should be a major reduction of the extremely costly, top heavy bureaucracy and paperwork initiatives at FSIS that have eliminated the funds necessary for consumer protection while obstructing inspectors from enforcing the law.

III. Non-political Science: There should be independently-developed public health standards, rapid laboratory testing and other National Academy of Sciences recommendations. The goal should be of reinforcing rather than replacing inspectors, who then could concentrate on stopping the abuses that make microbial contamination inevitable.

IV. Industry Self-inspections: There should not be delegation to industry of responsibility to vouch for the USDA seal of approval without corresponding industry accountability, both in terms of science and organizational checks and balances.

PROGRAM INTEGRITY

General

1. Institute a complete housecleaning of top Food Safety and Inspection Service management, because its industry bias and commitment to failed 1980's policies is too deeply ingrained for credible leadership of fundamental changes that are essential.

2. Appoint a food safety ombudsman who has the confidence of the inspection force, to informally monitor implementation of inspection reforms, investigate alleged deviations and report directly to the Secretary of Agriculture on significant findings.

3. Issue a directive that no inspectors may be harassed or disciplined for carrying out written instructions, procedures or regulations. The recent claim by an industry lobbyist from Cargill that Dr. Cross requested a list of inspectors who engage in "knee jerk * * * unreasonable or unusually severe" interpretations of a directive in which they had been instructed to "strictly" enforce a "zero tolerance" policy for fecal contamination has severely undermined inspector morale. Inspectors now fear that agency management has requested a hit list of inspectors who interfere with industry profits by carrying out food safety orders issued by agency management.

4. Issue a Department directive that informal, oral instructions to deviate from written food safety laws are without authority; inspectors are to enforce the laws on the books, not the verbal modifications that frequently are issued after meetings with industry representatives.

After the zero tolerance policy was announced, FSIS rescinded the straightforward procedural instructions transmitted by an area supervisor, and instead inspectors were told to receive informal guidance. At the same time, the Cargill lobbyist wrote his superiors that the zero tolerance policy only applies to "obvious" fecal contamination, a highly subjective standard at best. Subsequently some inspectors began receiving guidance that only green feces is "obvious," while brown feces is not. Similarly, they were told that feces mixed with mud no longer will be considered feces, but rather an "other material." Inspectors at other plants have not received this amazing interpretation. These types of oral interpretations have caused widespread cynicism among the inspection force.

5. Provide inspectors with training in microbiological hazards, including classroom instruction and a reference guide that could be used in the plants, followed up with continuing education.

6. Require that when industry wants to appeal an inspector's enforcement decision, it must be made in writing and lead to a written decision disclosing the legal and policy grounds for any decision to overrule an inspector. Currently the routine is for FSIS management to reject inspectors' actions after telephone calls or secret meetings with plant officials, without any record of the basis for a company's objections or the agency's for siding with industry.

7. Increase "correlations"—checks for consistency in applying food safety standards—as a counterpressure on veterinarians and inspectors who succumb to industry pressure.

Slaughter inspection

8. Significantly reduce line speeds until plants are redesigned to handle the faster speeds without compromising consumer protection. The lines are not long enough to accomplish all the public health tasks at faster speeds in the small space available before carcasses leave an inspector's station. Nevertheless, line speeds are *faster* at SIS-Cattle pilot plants during the Streamlined Inspection System phaseout. To implement this recommendation, time studies will be necessary that determine the square footage necessary to complete inspection duties at particular line speeds.

9. Extend the new beef carcass slaughter policies—zero tolerance for *E. coli,* as well as mandatory trimming of all visible fecal and ingesta contamination before a carcass can be rinsed with water, to boneless beef operations and all other species, including poultry.

10. Restore inspectors' authority to shut down plants for corrective action against conditions that inevitably will cause food safety hazards, even if the contamination has not yet occurred visibly. Issue a directive instructing FSIS supervisors and managers of your confidence in inspectors' judgments on the necessity to take these types of enforcement actions, including the less severe sanction of temporarily stop-

ping a line, and that Department policy will be to back the inspector's decision until completion of a written appeal process. (*See* recommendation 5, *supra.*)

11. Eliminate pre-evisceration carcass sprays. They are unnecessary for sanitation purposes since carcasses receive a post-evisceration spray ten minutes later, and their only practical impact is to add water weight that cannot be detected due to losing the base weight after organs are removed during evisceration. This leaves no data to check whether carcasses have returned to their original, or "green," weight.

12. Eliminate the practice of allowing carcass sprays in chill coolers. There is no public health justification for this practice, which only leads to consumers paying still further water weight at beef prices. The ostensible purpose for these sprays is to "bleach" fat so that it is white, and therefore more attractive. That is unnecessary, however. Traditionally carcasses were wrapped in shrouds that had been soaked in brine water. That accomplished the same purpose without adding water weight.

13. Eliminate FSIS approval for the current practice of ante-mortem cattle sprays outside the plants with untreated water containing sewage.

14. Eliminate FSIS approval for the current practice of reusing water after rinses of tripe that are full of feces and ingesta.

15. Restore inspectors' authority to enforce the written rules on chlorination of water in plant operations.

16. Eliminate FSIS defect criteria allowing approval of meat contaminated with "brown water" from mud, feces and/or other filth (shipped from Jack in the Box supplier Vons last year over an inspector's objections) and rain water that has dripped through leaking roofs (shipped to Desert Storm troops over an inspector's objection).

17. Remove the partitions that keep inspectors isolated in their stations and obstruct their view of the kill floor.

18. Require the addition of occupational safety equipment necessary to prevent carpal tunnel syndrome, respiratory conditions and other disabling conditions. Examples of necessary facilities that regularly do not exist include forearm rests, chairs, high enough inspection stands, adequate lighting and fans.

19. While retaining organoleptic functions necessary to catch symptoms, restore mirrors at inspection stations—not as a substitute for, but to reinforce inspectors—to increase visibility, particularly necessary because there is less time to look due to faster line speeds.

20. Restore separate inspection of kidneys removed from the carcass, instead of forcing the inspector to view in place with other organs. Kidney inspection affects whole carcass disposition, because symptoms easily identifiable there can expose diseases that will not be caught in more hidden portions within the carcass.

Processing inspection

21. Remove the red tape that obstructs inspectors from sending samples of suspect products for laboratory tests. Currently the testing must first be approved by a Regional Residual Officer, who can only be contacted by circuit supervisors who on occasion have been unavailable to inspection personnel for weeks. The red tape prevented timely testing for lead poisoning of SIS–C meat that arrived at a processing plant contaminated with shotgun pellets.

22. Scrap the Performance-Based Inspection System (PBIS) as a computer scheduling system that controls inspectors, and instead use it as a device to trend public health threats based on input from inspectors.

If America's food supply truly is the world's safest, PBIS assignments do not leave inspectors enough time for basic tasks that have earned that claim—checking the temperature of cooked products; checking the ingredients that go into lunchmeats and sausage; and routinely taking samples for regular laboratory testing. Instead, computer schedules have diverted them to repeatedly checking locker rooms, lunchrooms, bathrooms and parking lots on matters that are largely peripheral to consumer safety.

Further, the time provided for significant PBIS tasks that do appear in schedules assume compliance. They do not leave enough time for responding to problems. Unfortunately, inspectors' performance appraisals in part are based on meeting the time allotted for scheduled tasks.

23. Eliminate time-consuming petty paperwork burdens built into PBIS that minimize inspectors' presence in the plants, which is essential for deterrence and to catch violations. Limit inspector PBIS input to reports of violations that reflect significant public health threats or require significant enforcement action.

24. Eliminate the PBIS classification of "acceptable with variations," which rigs the data base by creating the appearance of lawfulness when there have been numerous violations during an inspection.

25. Eliminate the inconsistencies for which violations are placed on processed Deficiency Records, the enforcement record for the PBIS system.

26. Restore inspectors' authority to catch and enforce water weight violations at processing facilities. Because they no longer are permitted to identify and write up these violations, products such as ham are going to commerce despite containing well over 30-percent water and 10-percent fat.

27. Restore the "green weight" tests for processed foods. Products pumped with formulated solutions must return to their original weights to avoid consumer fraud. This test has been functionally eliminated in the aftermath of the failed Discretionary proposal.

28. Eliminate the red tape built into the PBIS Product Deficiency Record (PDR) system before inspectors can act against food safety violations. Previously inspectors could order appropriate corrective action on the spot. Now they must fill out a PDR and wait for it to go through three layers of review, a process which on occasion has taken over a year.

II. BUDGET CONTROLS

29. Fund additional inspectors by eliminating the expensive, labor intensive PBIS computer scheduling system. It relies on large numbers of programmers, analysts and clerical personnel to administer a system that has proved counterproductive for food safety. When FSIS reviewers find a processing facility out of control, a common solution is to suspend PBIS schedules and restore inspectors' prior freedom to identify violations.

30. Strive wherever possible to streamline management, instead of streamlining inspections. The number of management layers is unprecedented. The more that FSIS deregulated during the 1980's, the more that personnel were moved from the field to the office.

31. Eliminate the 26 Area Offices entirely. They originally were established to monitor State inspection programs, but FSIS now conducts little State oversight. The Area Offices currently function mainly to collect data for PBIS quarterly reports—data that could be sent directly to the region or Washington, DC. Policy decisions are virtually never made at the Area level.

III. NON-POLITICAL SCIENCE

32. Implement public health-based disease and microbial contamination standards as the basis for inspection decisions. The standards should be developed by the National Academy of Sciences to assure independence from the political manipulation and lobbying so common at FSIS.

33. Develop a rapid laboratory testing program approved by the National Academy of Sciences, as an insurance policy for USDA's seal of approval. Laboratory test results always have been vulnerable to manipulation, however. The tests should be used to reinforce, not replace, inspectors. Similarly, violations of USDA's food safety regulations should not be ignored merely because a product passes the rapid laboratory test.

34. Provide inspectors with reference materials on legal standards for all forms of adulteration which they may realistically encounter, even if not covered by USDA standards. For example, products have gone out despite contamination from insecticides covered by State law, because the bug spray was not in USDA's regulations.

35. Require objective basis for the "critical," "major" and "minor" classifications in the PBIS "Deficiency Classification Guides." Without any explanation in many cases, these categories have been drastically changed to reduce consumer protection. For example, formerly inspectors could stop operations when a plant has standing water, a bacteria breeding ground. Now standing water is classified as "minor," so plants can and do leave it on the floor for up to three weeks without the inspector being able to act.

36. Eliminate the practice of getting second opinions from USDA facilities when a company's own laboratory test results come out positive for illegal conditions, such as has occurred with *E. coli.*

37. Restore the practice of providing inspectors with documented confirmations of laboratory tests results—records instead of mere telephone calls with a message not to worry.

IV. INDUSTRY SELF-INSPECTIONS

38. Establish a structure in which corporate quality control (QC) programs reinforce FSIS inspectors, instead of acting in parallel or competition, as often occurs currently. Corporate QC programs that could double the effectiveness and coverage of USDA's program are being largely wasted, or used as company devices to rebut Federal findings of food safety violations.

39. Establish authority for inspectors to suspend QC, Total Quality Control (TQC) and Partial Quality Control (PQC) programs when plants fail to adhere to program commitments.

40. Cancel the current Hazard Analysis Critical Control Point (HACCP) pilot program and start over from scratch under guidelines developed by the National Academy of Sciences as part of an overall NAS program to modernize food inspection. The current HACCP system has lost all credibility with inspectors, because: Its public health standards have been set entirely by industry; it does not go beyond the critical control points currently covered by USDA inspectors; and as seen in the pilot plants to date only will result in corporate QC departments without internal checks and balances (whistleblower protection, qualifications and training standards, etc.) acting as inferior substitutes for USDA personnel enforcing food safety laws at the same locations.

The recommendations listed below are intended to develop a genuine HACCP program for modernizing inspection.

41. Operate from the premise that HACCP will be additive, rather than substitutive, for direct product inspection by USDA inspectors. In particular, do not permit HACCP to be a vehicle that restricts a Federal inspector's flexibility and freedom to look.

42. Require that risk assessment as defined by the *National Academy of Sciences* be a cornerstone for any approved HACCP program.

43. Require objective data to support the location of critical control points. At previous HACCP workshops, the location of critical control points around which HACCP operates has reflected the political consensus of industry representatives, rather than the judgment of objective data or even the judgment of USDA experts.

44. Develop empirical, science-based microbiological standards as a precondition for developing HACCP programs.

45. Require empirical testing for the superiority of any HACCP plans over previous inspection models as a precondition for approval.

46. Permit public comment for all HACCP programs, whether generic or plant-by-plant.

47. Require full public access to all HACCP procedures and public health records. Under the Streamlined Inspection System, USDA previously has denied public access to the corporate QC procedures, claiming that the rules in part underlying USDA's seal of approval are corporate "proprietary information."

48. Require that records of food safety violations be publicly available, as are equivalent records of inspections conducted by USDA's own personnel.

49. Require as a condition for approval of any HACCP system that all plant personnel have whistleblower protection equivalent to that available for Federal personnel.

50. Require that any approved HACCP program have quality assurance standards that meet the standards of professional associations such as the American Society for Quality Control.

Question 2. What specific recommendations do you have for reducing these types of foodborne illnesses?

Answer. FSIS should:

- Adopt a public health focus in meat and poultry inspection
- Base a new inspection system on scientific proof of the impact on human health of each of the procedures and requirements of the inspection system
- Develop rapid diagnostic procedures for detecting microorganisms, especially species of *Salmonella, Campylobacter, and E. coli*
- Develop and put into effect on-line tests for microbial contamination
- Develop an adequate system to test for chemical residues in meat and poultry
- Base any pathogen reduction plan on a full risk assessment:

—Hazard Identification
—Dose-response assessment
—Exposure assessment
—Risk characterization

- Define pathogenic bacteria as "added substances," and establish that both raw and processed products are adulterated if they contain enough bacteria that the product may be injurious to health
- Ask FDA to establish standards for microbial contamination of meat and poultry
- Require on-farm "good animal husbandry practices" comparable to FDA-mandated Good Manufacturing Processes (GMP) requirements of food processors
- Establish an animal identification and traceback system
- Adopt other pre-market protective activities including random testing for infectious agents; setting standards for sanitary shipping of live animals; requiring thorough cleaning of all animals before slaughter; conducting random pre-slaughter tests for infectious agents; implanting electronic devices in high-risk animals, and conducting random microbial testing of rejected animals
- Establish Federal standards for HACCP programs including: Identifying points at which contamination may occur, instituting processes to prevent contamination, and requiring training and certification of plant quality-control staff
- Develop and implement improved regulatory tools for use by plant and inspectors including: Statistical sampling plans for bacterial and chemical contaminants; rapid on-line tests for random checks of bacterial contamination of raw and processed products
- Provide whistleblower protection for those plant employees who protect the public from misfeasance or mistakes because, in absence of continuous inspection, plant employees take on a large measure of responsibility for protecting human health
- Mandate labels on all meat and poultry products stating that they may contain harmful bacteria and providing appropriate handling instructions
- Require temperature-abuse devices on all meat and poultry packages
- Make all plant compliance records available to the public

QUESTIONS SUBMITTED BY SENATOR GORTON AND ANSWERS THERETO

Question 1. One of my constituents in the Tri-Cities, Jack Richardson, has a granddaughter who is suffering from the effects of *E. coli* tainted meat. Mr. Richardson is looking for a silver lining in the *E. coli* outbreak. He hopes that the USDA will now look more closely at food irradiation. What are your thoughts, Secretary Espy?

Answer. First, I am very sorry to hear about your constituent's granddaughter. I sincerely hope she is on her way to a full recovery.

USDA believes it must look at all avenues, including new technology, to improve the safety of meat and poultry products. Many scientific groups in the United States and internationally have endorsed the use of food irradiation as a method of improving food safety.

USDA's Food Safety and Inspection Service (FSIS) must petition the Food and Drug Administration (FDA) to receive approval to permit the irradiation of meat and poultry. FSIS has already received FDA approval for the irradiation of pork for *trichinae* control and for fresh and frozen poultry to control bacteria. FSIS plans to give immediate priority to research to support a petition to FDA for the approval of irradiation for red meat. I must emphasize, however, that safe food handling would continue to be necessary for irradiated foods since some pathogens may survive the process or be reintroduced after the process. I have enclosed a packet of materials about irradiation for your use. [The submitted material is retained in the committee file.]

Question 2. Food safety has been a concern of mine for many years. Two years ago I introduced legislation which was signed into law that was meant to eliminate the deplorable practice known in the trucking industry as "backhauling." Backhauling is the practice of shipping inedible dangerous products one way and then shipping food on the return trip. Often times this occurred without even the minimal cleaning of the truck. We heard about garbage hauled in a truck only to haul sides of beef on the return trip. Obviously, this poses great risks of contamination—past the time that the meat had been inspected at the slaughterhouse.

It is my understanding that a notice of proposed rulemaking is pending signature by the Secretary of Transportation. The law provided that the Secretary of Transportation would work in consultation with the Secretary of Agriculture. Will you agree to look into this matter and urge the Secretary of Transportation to issue the notice of proposed rulemaking so that we may move forward with implementing this law?

Answer. I appreciate your concerns about this issue. As you know, the Advanced Notice of Proposed Rulemaking (ANPR) was published in the Federal Register on

February 20, 1991. It is my understanding that the Secretary of Transportation is currently reviewing the proposed rule on backhauling. You can be sure of the complete cooperation of USDA once this rule is finalized.

Question 3. Food and meat inspection involve many industry groups. As a former Member of Congress you know how very important it is to work with industry and other groups in forming workable and lasting solutions to problems. Mr. Secretary, will you involve industry, science and consumer groups in your efforts to address meat inspection and safety problems?

Answer. I agree that it is critical to work with industry, science, and consumer groups not only to address meat inspection and safety problems, but also for other issues that come before the Department. I strongly support the input and involvement of those who are interested in meat and poultry issues. As a matter of fact, I recently met with FSIS whistleblowers, consumer groups, and labor interests to get their thoughts on how meat and poultry inspection can be improved.

In addition, FSIS has two advisory committees that are addressing a variety of inspection and safety issues. FSIS solicited comments on the microbiological baseline study from a variety of consumer groups, industry groups, and noted scientists in academia and industry before proceeding with that initiative.

We plan to continue these efforts in the future. For instance, we recently decided to hold nationwide public hearings in the spring on our Track I and Track II programs, which comprise FSIS' strategy for the future. We are working to schedule these hearings in diverse geographical locations in order to ensure that all interested constituents have the opportunity to participate.

Question 4. You told the Washington State Senate that your staff is reviewing proposals for improved meat inspection standards. When, specifically, can Congress expect to see this proposal?

Answer. FSIS has developed a Pathogen Reduction Program that details the actions it plans to take at key points from the farm to the dinner table to reduce the occurrence of foodborne microorganisms. A copy of that document is submitted to the record for your review. [The submitted material is retained in the committee file.]

Question 5. In the short term, what advice do you have for the people of my home State? What steps can they take to avoid further outbreaks of *E. coli* or other foodborne contaminants?

Answer. USDA is committed to reducing microbiological contamination in meat and poultry. However, we are not able to guarantee a pathogen-free raw product. For that reason, consumers will always need to follow safe food-handling practices. The advice we have provided on our toll-free USDA Meat and Poultry Hotline (1–800–535–4555) and through our many food safety publications remains the same. Consumers should take special care to cook meat and poultry thoroughly and handle it carefully. Beef that is cooked to an internal temperature of 160 degrees and handled properly is safe. Ground beef should be cooked until there are no pink juices. For poultry, we recommend that consumers cook white meat to 170 degrees, and the whole bird or dark meat to 180 degrees. Consumers can order the FSIS publication "A Quick Consumer Guide to Food Handling" by writing the Consumer Information Center, Pueblo, Colo. 81009.

It is more difficult for consumers to control food safety when they eat at restaurants and other large-scale feeding establishments. Consumers can, however, request that foods be cooked to medium or well-done. In addition, they can examine the product before eating it. Hamburgers with a pink interior should be returned for further cooking. Poultry that appears to be undercooked by its consistency or color should also be returned.

Question 6. Washington State University (WSU) is currently conducting research on the *E. coli* bacteria. Is the U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA) or Centers for Disease Control (CDC) familiar with the research being done at WSU?

Answer:

USDA

USDA is familiar with the Washington State University (WSU) research funded by the International Life Sciences Institute and conducted by Dr. Dale Hancock. Also, between September 1992 and March 1993, Dr. Hancock was a visiting analytical epidemiologist with USDA's Animal and Plant Health Inspection Service in Fort Collins, Colorado. During this period, Dr. Hancock conducted fecal sampling for *E. coli* 0157:H7 as part of the National Dairy Heifer Evaluation Project. This work was

conducted in order to estimate the national and regional prevalences of the organism and to provide insights regarding risk factors for infection.

USDA is committed to using research conducted at land-grant and other universities and other research institutions to improve the safety of meat and poultry. USDA maintains a dialog with other researchers in a number of ways. For instance, FSIS is a member of the organizing committee for the Food Safety Consortium, which was established through a USDA Cooperative State Research Service (CSRS) special grant, approved by Congress in 1988. The Consortium consists of three member institutes—the University of Arkansas, Iowa State University, and Kansas State University. Coordinated research projects among the universities are being conducted on prevention, detection and removal or inactivation of pathogenic microorganisms.

USDA also keeps abreast of ongoing research on food safety through the Agricultural Research Service (ARS), which conducts research at the request of FSIS and other USDA agencies, and by participating in scientific meetings in the United States and abroad.

FDA

FDA is not aware of particular ongoing research at Washington State University. FDA does keep current on new developments concerning *Escherichia coli* 0157:H7 as they are reported in the scientific literature or when discussed at national bacteriological meetings.

CDC

CDC researchers are familiar with and have consulted on the research conducted by Dr. Dale Hancock, of Washington State University, in conjunction with the National Animal Health Monitoring System of the USDA. We feel that this sort of research is critical to answering the many questions we have about the ecology of *E. coli* 0157:H7 on farms.

Question 7. Preliminary WSU research on *E. coli* concludes that the key to controlling *E. coli* outbreaks lies at the level of the cattle farm. Has research conducted by USDA, FDA or CDC on this subject come to a similar conclusion?

Answer:

USDA

The National Academy of Sciences, which has evaluated various aspects of FSIS programs at their request, has advised that control of foodborne pathogens will require interventions at several key points in the food distribution system. The farm is one of these points.

National surveys to determine the prevalence of this organism in animal products at slaughter have been conducted by FSIS. Our results, which appear to be consistent with those obtained by WSU and APHIS, show a low prevalence of *E. coli* 0157:H7 in animals. For that reason, we believe that on-the-farm interventions would be helpful if we can target those infected animals.

FDA

See response to question 8.

CDC

Better understanding of the flow of *E. coli* 0157:H7 is needed at all levels. In an extensive review article on *E. coli* 0157:H7 published in 1991, and in a shorter extract published in 1993 (Attachments 3 and 4), CDC researchers stated that there was a great need for better diagnosis and reporting of human infections with this organism. On the subject of animal and slaughter plant research, CDC researchers concluded as follows:

> Studies of the ecology of *E. coli* 0157:H7 and other Shiga-like toxin-producing *E. coli* pathogens on dairy and other farms are needed to determine risk factors for carriage of these organisms on farms and in individual animals. Studies of the mechanisms by which meat becomes contaminated with *E. coli* during slaughter and processing, and institution of methods to decrease this contamination are critically needed. Regulations are needed to require that cooked hamburger patties and other meats be sufficiently precooked to kill pathogens. Finally, there is a need for food service personnel and consumers to be aware that all but the most well-cooked hamburger may still contain viable *E. coli* 0157:H7 and that consumption of insufficiently cooked ground beef can cause serious illness, especially in children and the elderly.

Question 8. Even after two years of research, WSU researchers are still left without answers to very basic questions:

—When do cattle become infected? Is infection of baby calves important or can new infections happen to older calves as well?
—How long do infections last in cattle? Is it lifelong or transient?
—How do manure management systems and feeds and feeding influence cattle infections with this bacterium?

Can USDA, FDA and CDC provide answers to the aforementioned questions?
Answer:

USDA

The studies conducted by WSU researchers are among the first research studies being conducted for on-farm control of this organism. Unfortunately, research on control of specific organisms in animals will require time to develop specific answers.

FDA

FDA research is normally focused on the safety of food itself. This focus includes prevention of the contamination of animal tissue used for human food; in general, such contamination could be introduced via animal feeds, water or drug injection. While there is preliminary information that *E. coli* 0157:H7 is associated with dairy cattle, the nature or route of infection has not been linked to the products that FDA regulates. Because that link is still hypothetical, FDA has not applied our limited research resources to the issues raised in this question.

CDC

CDC researchers agree that these questions about the ecology of *E. coli* 0157:H7 on dairy farms are important, and have conducted a limited amount of field work to answer some of them (Attachment 5). This work demonstrated that roughly one percent of animals on farms with *E. coli* 0157:H7 actually carry the organism, that the youngest animals are most likely to carry it, and that although the individual animal did not seem to carry the organism for long, the same strain could persist in the herd for at least a year.

Other critical questions have been raised by work at CDC on this organism. Answers to these basic questions will only come from better surveillance of the human infections, and more support for public health research to answer them. Some of these basic questions are:

- What is the frequency of human infections with *E. coli* 0157:H7 in the United States, and is it increasing?

National data are not available because few clinical laboratories look for this organism routinely, and few State health departments request laboratories that identify it in patient specimens to report it to the public health department. Washington State is one of the few States where this infection is reported. Good surveillance at several sentinel sites would provide new and important data on national trends of this infection, and ongoing risk assessment of possible sources of infection. Efforts are needed to improve diagnosis in medical laboratories and to make this infection reportable throughout the United States. This will speed up recognition of outbreaks and action to prevent further cases. More effort is needed in public health laboratories to develop methods for differentiating strains from each other. This will help link related cases and detect widely distributed and otherwise unrecognized outbreaks.

- Once surveillance is improved, and outbreaks are detected swiftly, how can local, State and federal public health departments most effectively prevent further cases from occurring?

Developing effective intervention means understanding how infection is transmitted well enough to interrupt spread, and understanding the points where effective public health control can occur. Important possible public health prevention measures include identifying and recalling contaminated foods, identifying and changing hazardous cooking practices, chlorinating unsafe water supplies, closing polluted swimming beaches, and intervening in child care centers to halt transmission. The issue of spread in child care centers is particularly challenging; more research on how to stop transmission in that setting would prevent future illness and deaths. Efforts to speed reporting and intervention at all levels will identify outbreaks earlier, and will prevent further illness from occurring, but will also require additional resources.

- There are other strains of *E. coli* besides 0157:H7 that produce toxins similar to those produced by 0157:H7. How big a public health problem are these other strains of *E. coli* bacteria? If they are important, how are they transmitted and how can they be prevented?

These strains may cause similar illness to *E. coli* 0157:H7, and are known to be common in cattle, but are currently only identified by highly specialized laboratory techniques. Applying better diagnostic methods in the setting of heightened public health surveillance would answer this question as well.

Question 9. How much money does USDA, FDA and CDC spend to research foodborne contaminants—and *E. coli* specifically— each year?

Answer:

USDA

USDA spends its research funds in a variety of ways. For instance, the Cooperative State Research Service (CSRS) supports foodborne contaminant research through formula funds provided to State Agricultural Experiment Stations (SAES) under the Hatch Act, the 1890 Colleges and Tuskegee University under the Evans-Allen Program, and to the SAES and schools or colleges of veterinary medicine under Animal Health and Disease Research, Section 1433. Funds also are provided through the Special Research Grants Program and the National Research Initiative Competitive Grants Program.

ARS carries out food safety research at 16 of its major research centers located across the country. Over half of ARS's research dollars are devoted to research that specifically responds to needs identified by FSIS. Although it occasionally conducts special studies on its own, FSIS carries out its research largely through ARS.

According to the most recent figures available, USDA spends approximately $1,323,000 on *E. coli* 0157:H7 research each year. The breakdown by agency currently is as follows: ARS—$297,000; CSRS—$646,000; and FSIS—$380,000. USDA spends approximately $15,237,000 to research other foodborne pathogens. The breakdown by agency currently is as follows: CSRS—$5,817,000; ARS—$7,720,000; and FSIS—$1,700,000.

FDA

FDA spent approximately $32.4 million on food safety research in FY 1992. $10.05 million of that was spent on all microbiology research and $375,000 was spent on research of the *E. coli* microorganism.

CDC

CDC obligated approximately $0.5 million for *E. coli* research in FY 1992. For research on foodborne infections, CDC spent approximately $3.0 million in FY 1992. In FY 1993, CDC anticipates obligating about $2.9 million for these program activities.

INTERIM GUIDELINE TO ASSURE THE MICROBIOLOGICAL SAFETY OF PRECOOKED MEAT PATTIES

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INTERIM GUIDELINE TO ASSURE

THE MICROBIOLOGICAL SAFETY OF PRECOOKED MEAT PATTIES

Precooked foods are a rapidly growing segment of the foodservice and retail market. This guideline pertains to one group of these products -- precooked meat patties, but the general principles may be applicable to certain other ground meat products.

Unlike ham and roast beef, precooked meat patties are much thinner and have more rapid heating and cooling curves. They are cooked by high temperature, short time processes and a separate guideline is in order.

This guideline addresses all aspects of pattie processing, but focuses particularly on achieving and verifying adequate heat processing. Three options for accomplishing this are:

1. Attaining an instantaneous minimum temperature.

2. Attaining a prescribed temperature and holding that temperature for a required time.

3. Measuring total lethality induced during cooking and cooling.

Product and Processing Methods

The wide variety of product formulations, product sizes, heating techniques and processing equipment makes it impractical in this publication to describe any particular process. Each processor must identify the critical control points for each product and process and determine the specific requirements which will assure compliance with safety standards. This guideline will assist in identifying critical control points that are common to the many processes.

Raw Materials

The quality of precooked meats can only be assured by using raw materials of good microbial quality. The condition of raw materials cannot be predicted by age or temperature alone. Routine evaluation of raw material suppliers is the most reliable procedure for assuring the acceptability of incoming raw materials. In order to assure optimum quality raw meat temperature should not exceed 40°F.

Frozen meat should be defrosted in a controlled environment to minimize microbial growth. Grinding from a frozen state is one of several options for controlling bacterial growth.

Formulation and Forming

A uniform raw pattie is the first step in obtaining uniform heat processing. The response to any type of heating is influenced by the fat, moisture, and protein content and the addition of extenders and seasonings. Controlled blending procedures can be effective in minimizing cold spots within a pattie. Close control of temperatures from batch to batch are equally important.

Heat Processing

The diversity of cooking equipment and processing conditions makes the control of cooked product temperatures a very critical and challenging point of the process. Some types of equipment are inherently more variable than others. Product temperatures from a well controlled cooker may have a deviation of ± 3°F across the belt, and a much broader range may occur in a less well controlled process. It is of utmost importance to know the characteristics of products and processes and that the target temperature is set to ensure that all product reaches the desired minimum internal temperature. Poor control and variable end-point temperatures must be compensated by raising the process target temperature. Raising the temperature will usually be detrimental to palatability and yields, but cannot be avoided in poorly controlled processes.

Chilling

Patties should be chilled below 34°F before boxing for the freezer. Rapid freezing prior to boxing will give added protection to the quality of the product, but is not necessary to control microbial growth.

Temperature Measurement

The accurate measurement of the internal temperature of individual patties is essential to good process control. Because dial thermometers are difficult to place in the geometric center of a pattie and they lack responsiveness, they are not recommended for this task.

The recommended instrument is an electronic thermometer with a needle-like probe. Typically these are accurate to 0.1°F and give the highest reading within 5 seconds.

Measuring the average temperature in the center of stack of cooked patties is inappropriate because it does not give an accurate temperature assessment of the process. A process must be evaluated on the basis of minimum temperature of individual patties taken across the full width of the belt.

The frequency of temperaturing must be determined for each process and should be part of every Partial Quality Control (PQC) or HACCP program.

Temperature probes used to monitor cooked and raw meats must be sanitized before changing from raw to cooked products.

The temperature probes should be calibrated daily and checked against a standard mercury thermometer to ensure accuracy.

Safe Processing Temperatures

The microbiological safety of precooked meat patties is dependent on the thermal process. Based on existing information, a minimum 4D process for the destruction of Salmonella is required. (Table 1)

In order to assure that the minimum thermal process is achieved, certain factors must be understood and controlled. Examples of critical control points which may affect the thermal process include the following:

A. Product

1. Pattie composition, i.e., fat, moisture, density, the use of extenders, etc.
2. Physical dimensions of the patties prior to and during the cooking process.
3. Raw pattie temperature and uniformity of raw pattie temperature.

B. Cooking

1. Overlapping patties
2. Spacing between patties

3. Belt speed

4. Cook temperature

5. Relative Humidity

6. Air velocity

C. Equipment and Facility

1. Heat source in oven

2. Maintenance of temperature control within oven

3. Heat flow pattern

4. Post-oven environmental temperature

5. Oven equipment maintenance

6. Use of air or water for fat removal after cooking

Three options are available which processors can use to assure that a minimum 4D process is attained. The selection of which option to use depends upon the processing equipment, the layout of the equipment, and the ability of the processor to limit variability and to monitor and control the process. The three options are:

A. cooking to a minimum internal temperature

B. cooking to a minimum internal temperature and holding for a minimum length of time

C. applying a thermal process which provides a minimum lethality equivalent to a 4D process.

In option A all product must reach a specified minimum internal temperature of 155°F. at some point during the process.

In option B all product must reach a specified minimum internal temperature and held for sufficient time to achieve a 4D process (see Table 1).

In option C the sum of the lethality values (Table 2) attained during the heating and cooling cycles must meet a minimum of 0.686 which is equivalent to a 4D Salmonella process (Goodfellow and Brown, 1978). This concept is used for the production of low acid canned foods as regulated by FDA or USDA. The concept was described by Shapton et al (1971) for application to foods given a pasteurization process. An example of the application of this concept to precooked meat patties is attached.

Process Control

Each process must be reenforced by a quality control program which addresses each of the critical points (HACCP). Microbiological safety starts with minimizing contamination from the environment and personnel. Starting each day with a cleaned and sanitized plant and maintaining sanitary work habits throughout the day is essential. Avoiding any traffic between raw material areas and processed product areas helps to avoid recontamination of product after it is cooked.

Particular attention must be directed to the inherent variability of each individual product and process.

Regardless of whether option A, B, or C is used to assure a 4D process, all calculations must take into account the temperature variability associated with the cooking process.

Studies must be conducted to determine the variability of the process. If a process has a 10 degree variability, the lowest temperature would be used for the determination of a minimum 4D process; i.e., the lowest temperature is the lower control limit. Examples of the three methods would be as follows:

Method A

Where an instantaneous temperature of 155 degrees is required. If the process has a 10 degree variability, the target temperature would be set at 165 degrees (155 degrees required minimum + 10 degree variability).

Method B

Attaining a prescribed temperature and holding at that temperature for a required time. If a process was set for minimum temperature of 152 degrees and a holding time of 26 seconds (Table 1), then a process with a 10 degree variation would require the target temperature to be set at 162 degrees (152 degrees required + 10 degree variability).

Method C

If the total lethality is being calculated, the lowest temperatures achieved during the heating and cooling process would be used in determining the process lethality.

In addition, under all circumstances, provisions must be made to identify deviations when the product leaves the heat chamber to assure that individual patties can be removed immediately or a portion of the production can be flagged for retention following the chilling or freezing process.

The Catalase test is not at this time a substitute for regular temperature monitoring, but processors can utilize the method to avoid underprocessed product.

Product Identification and User Instructions

In many instances, the labels of precooked patties are not informative and in these instances further instructions for the end user are necessary. Products processed under these guidelines are fully cooked. Products which do not meet these guidelines should be considered to be raw and labeled accordingly. However, some processors may choose to have their fully cooked products labeled with instructions to reheat to pasteurization temperature to eliminate any potential problems that may result from recontamination during distribution and handling.

Summary

The production of microbiologically safe precooked meat patties is dependent on prescribing a thermal process which will attain the equivalent of a 4D process in all parts of the product. A well defined quality program is essential for all operations.

###

OPTION C: INTEGRATED LETHALITY CONCEPT

The concept of process lethality is quite simple in theory, but it is considerably more difficult to implement in practice. The aid of an expert process authority is required to assist with a process review and establish a control and monitoring program to assure the adequacy of a thermal process.

When patties are cooked, microbial destruction occurs during both the heating and cooling cycles. This knowledge permits the application of a more sophisticated approach toward thermal processing than is possible in the first two options described on pages 4 and 5.

Fortunately, salmonellae are destroyed in a very predictable manner when subjected to moist heat as when meat patties are cooked. This predictable nature is quantifiably expressed by two terms, a D value and a z value. The D value or decimal reduction time is the time in minutes to destroy 90% (i.e., 1 log reduction) of the microorganisms present at a specific temperature.

As the temperature is changed, the rate of thermal destruction of salmonellae will change. Salmonellae die faster at higher temperatures than at lower temperatures (see Table 1). The z value is the number of °F required to cause a change of 90% in the number of microorganisms killed in a specific period of time. For example, the z value for Salmonella is 10°F. This means that if the product is heated at 160°F rather than 150°F, there will be a 90% (or 1 log) increase in the number of Salmonellae killed in the same time period.

The Lethal Rate table (Table 2) shows the relationship between the effect of temperature in the range of 130.0 to 170.9°F relative to the destruction of Salmonellae at 150°F which has a z value of 10°F.

From the lethal rate table it is possible to establish a thermal process which is equivalent to a 4D process. A 4D process for salmonellae is simply a process which will result in a 4 log reduction of the number of cells.

The D_{150} value for most Salmonella is 0.1716 minutes; thus the required time at 150°F for a 4D process would be:

$$t = 0.1716 \times 4$$

$$t = 0.6864 \text{ minutes}$$

To utilize this concept the temperature history for the product must be experimentally determined during both heating and cooling portions of the thermal process (Figure 1).

Using values from the time-temperature curve (Figure 1) and the lethal rate table (Table 2), a thermal process evaluation table (Table 3) can be constructed. The first three columns of Table 3 are taken from Figure 1. Column 4 of Table 3 (lethal rate/minute) comes from Table 2 (lethal rates). Using the minimum temperature at a given time in the heat process, the lethal rate/minute is obtained from Table 2 to give column 4 of Table 3. For Table 2, whole degrees are in the left margin and tenths of degrees Fahrenheit are across the top of the page. Column 5 of Table 3 (lethality/time interval) is obtained by multiplying column 4 by the time interval at that temperature. For this example, the time interval is 0.25 minutes. Column 6 of Table 3 (total process lethality) is the accumulative total of column 5. When this total is equal to 0.686 minutes, a 4D process has been obtained. The one ounce patty example does not reach a total of 0.686 minutes. Table 3 shows it only gets to 0.682 minutes.

The time/temperature history for the product must represent the coldest point in the product at each time interval, i.e., it must be conservative. A sufficient number of readings must be taken at each time interval to ensure that the coldest spot in the product has been measured. The temperature must be determined with a known accurate, low mass, thermocouple. The time interval between readings should be constant and the shorter the thermal process, the smaller should be the time interval between readings. Product from each lane on the cooker belt must be evaluated.

A separate study is required for each product (size, shape, and formula) being produced. The details of each study must be documented and retained on file.

A new study must be conducted any time there is a significant change in the thermal processing equipment.

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TABLE 1

Thermal Death Curve for Salmonella in Beef Emulsions in Tubes (Derived from: Goodfellow & Brown 1976)

TEMP DEG.C	TIME DEG.F	4D TIME
60.0	140	6.87 (min.)
60.6	141	5.46 (min.)
61.1	142	4.33 (min.)
61.7	143	3.44 (min.)
62.2	144	2.73 (min.)
62.8	145	2.17 (min.)
63.3	146	1.73 (min.)
63.9	147	1.37 (min.)
64.4	148	1.09 (min.)
65.0	149	51.88 (sec.)
65.6	150	41.21 (sec.)
66.1	151	32.74 (sec.)
66.7	152	26.00 (sec.)
67.2	153	20.55 (sec.)
67.8	154	16.41 (sec.)
68.3	155	13.03 (sec.)
68.9	156	10.35 (sec.)
69.4	157	8.22 (sec.)
70.0	158	6.53 (sec.)
70.6	159	5.19 (sec.)
71.1	160	4.12 (sec.)
71.7	161	3.27 (sec.)
72.2	162	2.80 (sec.)
72.8	163	2.07 (sec.)
73.3	164	1.64 (sec.)
73.9	165	1.30 (sec.)

Lethal-Rate Table

(Equivalent Minutes at 150 F)

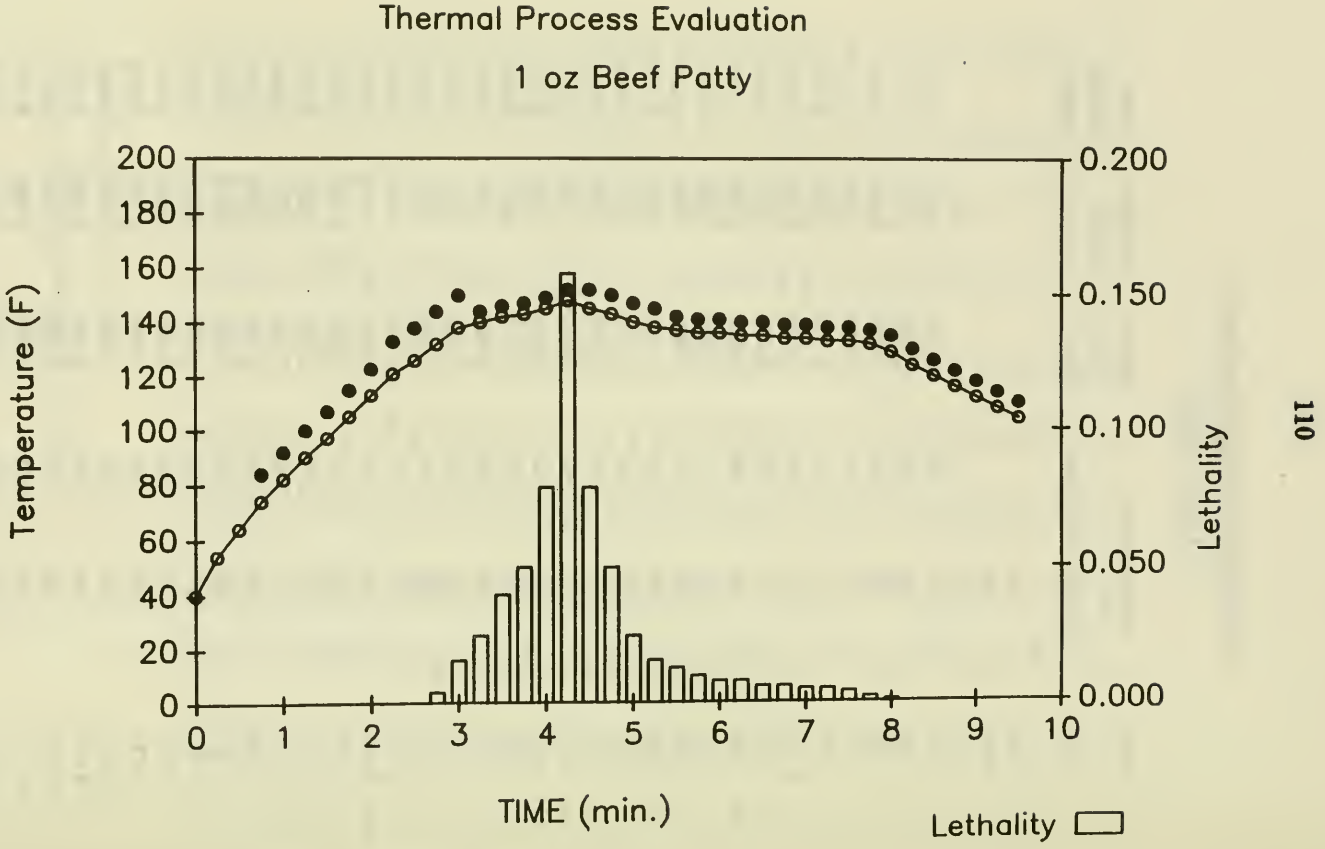
Temp. F	0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
130	0.010	0.010	0.010	0.011	0.011	0.011	0.011	0.012	0.012	0.012
131	0.013	0.013	0.013	0.013	0.014	0.014	0.014	0.015	0.015	0.015
132	0.016	0.016	0.017	0.017	0.017	0.018	0.018	0.019	0.019	0.019
133	0.020	0.020	0.021	0.021	0.022	0.022	0.023	0.023	0.024	0.025
134	0.025	0.026	0.026	0.027	0.028	0.028	0.029	0.030	0.030	0.031
135	0.032	0.032	0.033	0.034	0.035	0.035	0.036	0.037	0.038	0.039
136	0.040	0.041	0.042	0.043	0.044	0.045	0.046	0.047	0.048	0.049
137	0.050	0.051	0.052	0.054	0.055	0.056	0.058	0.059	0.060	0.062
138	0.063	0.065	0.066	0.068	0.069	0.071	0.072	0.074	0.076	0.078
139	0.079	0.081	0.083	0.085	0.087	0.089	0.091	0.093	0.095	0.098
140	0.100	0.102	0.105	0.107	0.110	0.112	0.115	0.117	0.120	0.123
141	0.126	0.129	0.132	0.135	0.138	0.141	0.145	0.148	0.151	0.155
142	0.158	0.162	0.166	0.170	0.174	0.178	0.182	0.186	0.191	0.195
143	0.200	0.204	0.209	0.214	0.219	0.224	0.229	0.234	0.240	0.245
144	0.251	0.257	0.263	0.269	0.275	0.282	0.288	0.295	0.302	0.309
145	0.316	0.324	0.331	0.339	0.347	0.355	0.363	0.372	0.380	0.389
146	0.398	0.407	0.417	0.427	0.437	0.447	0.457	0.468	0.479	0.490
147	0.501	0.513	0.525	0.537	0.550	0.562	0.575	0.589	0.603	0.617
148	0.631	0.646	0.661	0.676	0.692	0.708	0.724	0.741	0.759	0.776
149	0.794	0.813	0.832	0.851	0.871	0.891	0.912	0.933	0.955	0.977
150	1.000	1.023	1.047	1.072	1.096	1.122	1.148	1.175	1.202	1.230
151	1.259	1.288	1.318	1.349	1.380	1.413	1.445	1.479	1.514	1.549
152	1.585	1.622	1.660	1.698	1.738	1.778	1.820	1.862	1.905	1.950
153	1.995	2.042	2.089	2.138	2.188	2.239	2.291	2.344	2.399	2.455
154	2.512	2.570	2.630	2.692	2.754	2.818	2.884	2.951	3.020	3.090
155	3.162	3.236	3.311	3.388	3.467	3.548	3.631	3.715	3.802	3.890
156	3.981	4.074	4.169	4.266	4.365	4.467	4.571	4.677	4.786	4.898
157	5.012	5.129	5.248	5.370	5.495	5.623	5.754	5.888	6.026	6.166
158	6.310	6.457	6.607	6.761	6.918	7.079	7.244	7.413	7.586	7.762
159	7.943	8.128	8.318	8.511	8.710	8.913	9.120	9.333	9.550	9.772
160	10.000	10.233	10.471	10.715	10.965	11.220	11.482	11.749	12.023	12.303
161	12.589	12.882	13.183	13.490	13.804	14.125	14.454	14.791	15.136	15.488
162	15.849	16.218	16.596	16.982	17.378	17.783	18.197	18.621	19.055	19.498
163	19.953	20.417	20.893	21.380	21.878	22.387	22.909	23.442	23.988	24.547
164	25.119	25.704	26.303	26.915	27.542	28.184	28.840	29.512	30.200	30.903
165	31.623	32.359	33.113	33.884	34.674	35.481	36.308	37.154	38.019	38.905
166	39.811	40.738	41.687	42.658	43.652	44.668	45.709	46.774	47.863	48.978
167	50.119	51.286	52.481	53.703	54.954	56.234	57.544	58.884	60.256	61.660
168	63.096	64.565	66.069	67.608	69.183	70.795	72.444	74.131	75.858	77.625
169	79.433	81.283	83.176	85.114	87.096	89.125	91.201	93.325	95.499	97.724
170	100.000	102.329	104.713	107.152	109.648	112.202	114.815	117.490	120.226	123.027

Reference temperature = 150 F, z = 10 F

Prepared for the American Meat Institute (C) 1989

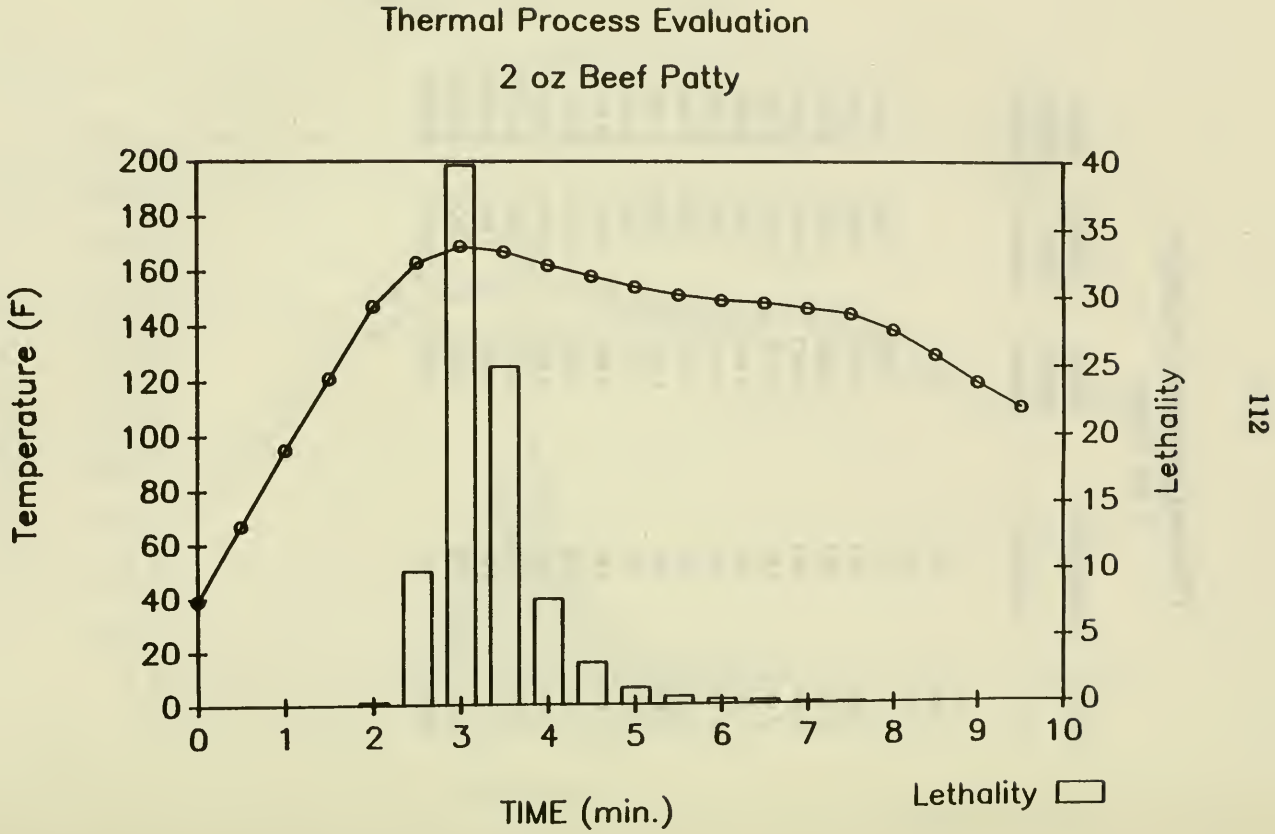
Thermal Process Evaluation
1 oz. Patty

Time	Temperature F		Lethal Rate/	Lethality /Time	Total Process
Min.	Minimum	Maximum	Minute	Interval	Lethality
0.00	40				
0.25	54				
0.50	64				
0.75	74	84	0.000	0.000	0.000
1.00	82	92	0.000	0.000	0.000
1.25	90	100	0.000	0.000	0.000
1.50	97	107	0.000	0.000	0.000
1.75	105	115	0.000	0.000	0.000
2.00	113	123	0.000	0.000	0.000
2.25	121	133	0.000	0.000	0.000
2.50	126	138	0.000	0.000	0.000
2.75	132	144	0.016	0.004	0.004
3.00	138	150	0.063	0.016	0.020
3.25	140	144	0.100	0.025	0.045
3.50	142	146	0.158	0.040	0.084
3.75	143	147	0.200	0.050	0.134
4.00	145	149	0.316	0.079	0.213
4.25	148	152	0.631	0.158	0.371
4.50	145	152	0.316	0.079	0.450
4.75	143	150	0.200	0.050	0.500
5.00	140	147	0.100	0.025	0.525
5.25	138	145	0.063	0.016	0.541
5.50	137	142	0.050	0.013	0.553
5.75	136	141	0.040	0.010	0.563
6.00	136	141	0.040	0.010	0.573
6.25	135	140	0.032	0.008	0.581
6.50	135	140	0.032	0.008	0.589
6.75	134	139	0.025	0.006	0.595
7.00	134	139	0.025	0.006	0.602
7.25	133	138	0.020	0.005	0.607
7.50	133	138	0.020	0.005	0.612
7.75	132	137	0.016	0.004	0.616
8.00	129	135	0.000	0.000	0.616
8.25	124	130	0.000	0.000	0.616
8.50	120	126	0.000	0.000	0.616
8.75	116	122	0.000	0.000	0.616
9.00	112	118	0.000	0.000	0.616
9.25	108	114	0.000	0.000	0.616
9.50	104	110	0.000	0.000	0.616


Thermal Process Evaluation
1 oz Beef Patty
Temperature (F)
200
180
160
140
120
100
80
60
40
20
0
0.200
0.150
0.100
0.050
0.000
Lethality
0
1
2
3
4
5
6
7
8
9
10
TIME (min.)
Lethality

Thermal Process Evaluation
2 oz Patty

Time Min.	Temperature F Minimum	Lethal Rate/ Minute	Lethality /Time Interval	Total Process Lethality
0.00	39			
0.50	67			
1.00	95			
1.50	121	0.000	0.000	0.000
2.00	147	0.501	0.251	0.251
2.50	163	19.953	9.976	10.227
3.00	169	79.433	39.716	49.943
3.50	167	50.119	25.059	75.003
4.00	162	15.849	7.924	82.927
4.50	158	6.310	3.155	86.082
5.00	154	2.512	1.256	87.338
5.50	151	1.259	0.629	87.967
6.00	149	0.794	0.397	88.365
6.50	148	0.631	0.315	88.680
7.00	146	0.398	0.199	88.879
7.50	144	0.251	0.126	89.005
8.00	138	0.063	0.032	89.036
8.50	129	0.000	0.000	89.036
9.00	119	0.000	0.000	89.036
9.50	110	0.000	0.000	89.036


Thermal Process Evaluation
2 oz Beef Patty
Temperature (F)
200
180
160
140
120
100
80
60
40
20
0
Lethality
40
35
30
25
20
15
10
5
0
0
1
2
3
4
5
6
7
8
9
10
TIME (min.)
Lethality

RESEARCH PROPOSAL to

American Meat Institute

Title: Use of Irradiation to Kill Pathogenic Bacteria in Ground Beef

Principal Investigator: Dr. Larry R. Beuchat

Co-Investigators: Dr. Michael P. Doyle
Dr. Robert E. Brackett

Address: Food Safety and Quality Enhancement Laboratory
Department of Food Science and Technology
University of Georgia
Griffin, GA 30223
(Tel: 404-228-7284)
(FAX: 404-229-3216)

Proposed Starting Date: March 1, 1993 (or date funds are received from AMI, whichever is latest)

Period of Requested Support: 1 year

Proposed Budget: $60,820

A. Introduction

Ionizing irradiation has been proposed for disinfestation of grains, pasteurization of fresh and dried fruits, vegetables and spices, inactivation of viruses, protozoa and helminths in meats and fish, and elimination of spoilage and pathogenic bacteria in meats, poultry, fish and shellfish (Thayer, 1990). Conditions of treatment have been proposed for virtually every class of fresh and processed food.

While the beef industry is interested in using irradiation to extend the shelf-life of its products, it also has keen interest in providing microbiologically safe products to the consumer. Thus, the fate of several bacterial pathogens, as influenced by irradiation treatment, has been studied extensively. Doses necessary to kill vegetative cells and spores of Clostridium botulinum have been reported (Anelis et al., 1979). Treatment conditions resulting in death of various populations of numerous Salmonella serotypes, Campylobacter jejuni, Listeria monocytogenes, Staphylococcus aureus and Aeromonas hydrophila have been investigated and reviewed (Kampelmacher, 1983; Thayer et al., 1986; Shay et al., 1988).

Notably absent from the list of pathogenic bacteria studied for their behavior when exposed to irradiation is enterohemorrhagic Escherichia coli 0157:H7. Manifestations of human illness caused by this bacterium principally include hemorrhagic colitis, hemolytic uremic syndrome (HUS) and thrombotic thrombocytopenic purpura (Doyle and Padhye, 1989). Several outbreaks of have been linked epidemiologically to consumption of ground beef. The presence of E. coli 0157:H7 in retail samples of ground beef, pork, lamb and poultry has been demonstrated.

The radiation resistance of non-pathogenic E. coli has been studied (Ma and Maxcy, 1981). Thayer and Boyd (1992a) studied the radiation resistance of E. coli 0157:H7 in deboned chicken meat, ground lean beef and steak tartar. They concluded that irradiation is an effective method for controlling this pathogen. However, D(kGy) values for E. coli 0157:H7 in ground beef have not been reported. Radiation sensitivity of L. monocytogenes in deboned chicken meat (Huhtanen et al., 1989), C. jejuni in ground beef (Tarkowski et al., 1984) and ground turkey (Lambert and Maxcy, 1984) and S. aureus in chopped beef (Erdman et al., 1961) and deboned chicken meat (Thayer and Boyd, 1992b) has been investigated. Most studies have involved the use of single strains of test pathogens. Furthermore, no reports have been made that compare radiation resistance of E. coli 0157:H7, L. monocytogenes, C. jejuni and S. aureus when subjected to treatment under the same set of environmental conditions.

Comparisons of research observations made by various investigators on the behavior of a particular pathogen are difficult because the conditions of treatment, e.g., the culture medium and growth temperature used to prepare inocula, the age of the cells, the composition and pH of the meat or medium in which cells are suspended during irradiation and the recovery medium, vary greatly from laboratory to laboratory. Sensitivity to irradiation may differ among strains of a particular pathogen.

The sensitivity of these pathogens to irradiation as affected by the level of fat in ground beef has not been reported. Product composition is known to influence the effectiveness (lethality) of irradiation toward microorganisms in general (Thayer et al., 1986), so it would not be unlikely that the dose required to achieve a desired reduction in viable population of E. coli 0157:H7, for example, in low-fat ground beef would be different from the dose required to achieve the same reduction in full-fat ground beef.

B. Objective

1. To determine the effectiveness of gamma irradiation (^{60}Co) treatment to kill E. coli 0157:H7, L. monocytogenes, Salmonella typhimurium, C. jejuni and S. aureus in ground beef.

C. Experimental Design and Methods

Research will be conducted at the Food Safety and Quality Enhancement Laboratory, University of Georgia in collaboration with Vindicator, Inc., Plant City, FL. Fresh ground beef will be the vehicle for testing the effectiveness of ^{60}Co irradiation on inactivation of five pathogenic bacteria. Parameters to be tested are as follows:

1. Ground beef: Fresh ground beef containing two levels of fat (10-14% and 26-30%) will be studied.
2. Test strains of pathogens: Five strains of each pathogen representing isolates from beef and humans suffering from illness caused by the pathogens will be investigated.
3. Temperature of treatment: Inoculated ground beef will be maintained at two temperatures (-10 to -14°C and 3 to 5°C) during irradiation treatment.
4. Irradiation dose: Irradiation will be applied with a ^{60}Co source with doses of 0, 0.25, 0.50, 0.75, 1.00, 1.25, 1.00, 1.50, 2.00 and 3.00 kGy.

Each experiment will be done in triplicate.

D. **Experimental Methods**

Methods for conducting experiments will be as follows:

1. Preparation of beef: Various cuts of raw beef will be purchased from a commercial source(s). Beef will be aseptically trimmed to remove the outermost 1-cm layer, thus reducing background microflora in the ground product prepared in our laboratory. Three replicates of uninoculated and inoculated ground beef will be subjected to all microbiological and chemical analyses.
2. Procedure for inoculation: Each pathogen will be cultured in Trypticase soy broth at 35°C; a five-strain mixture of 24-h-old cultures of each pathogen will be serially diluted in sterile phosphate buffer and added to ground beef to result in a viable population of $\sim 10^7$ cfu/g. Thoroughly mixed beef will be divided into 100-g subsamples, placed in plastic bags and formed into layers ~ 1 cm thick. Samples adjusted to 3 to 5°C and -10 to -14°C will be subjected to irradiation. Each pathogen will be tested individually.
3. Irradiation treatment: Packages of inoculated ground beef will be placed in cardboard containers and exposed to gamma irradiation (^{60}Co) for times sufficient to achieve desired doses (C.4., above). Treatment will be done at Vindicator, Inc., Plant City, FL.
4. Analytical procedures:
   a. Microbiological: Viable populations of pathogens will be determined using methods published by USDA-FSIS, the American Public Health Association (Vanderzant and Splittstoesser, 1992) and independent researchers, as necessary, to achieve maximum detection. Non-irradiated and irradiated samples will be analyzed as soon as practical, but not more than 24 h, after irradiation treatment. Samples will be maintained at appropriate temperatures (3 to 5°C or -10 to -14°C) during the periods between inoculation and irradiation treatment and between treatment and analysis. Three samples per dose will be tested.
   b. Chemical: The fat, protein and moisture contents will be determined using standard AOAC procedures.
5. Calculations and statistical analysis: D(kGy) values for pathogens in ground beef containing low and high fat contents and irradiated at two temperatures will be calculated. Appropriate statistical analyses will be done to determine if significant differences in values exist as affected by the independent and interacting effects of fat content and temperature of treatment.

E. **Reporting of Results**

Updates on progress and data obtained during the duration of the project will be supplied upon request of AMI. A detailed written report will be submitted to AMI within six weeks of the termination date of the project. Results of the project will be presented at a professional scientific meeting. A manuscript reporting the results of the study will be written for publication in a scientific journal, with proper acknowledgement of support from AMI.

F. **Time Frame**

Approximately the first two months of the project will be devoted to obtaining materials (test strains, media, chemicals, reagents, glassware, Petri dishes, etc.) necessary to conduct tests and microbiological and chemical analyses. Experiments on test pathogens will be conducted from the third to the eleventh month of the study. The twelfth month will be devoted to writing a detailed report.

G. **Budget***

1. Labor and Staff Benefits Postdoctoral Associate/Technician/Lab Helper	$35,520
2. Travel a. Six round trips (Griffin, GA - Plant City, FL) at $800/trip (includes airfare, car rental, one night's lodging and food) plus $800 for travel to professional scientific meetings for the purpose of reporting results of study).	5,600
3. Operating Supplies a. Includes costs for meat ($400), irradiation treatments ($4,000), media ($4,400), chemicals and reagents ($1,700), disposable petri dishes and pipettes ($3,800), glassware ($1,400), computer time ($1,000) miscellaneous expendable supplies ($2,000) and publications ($1,000).	19,700
4. Equipment	0
Total Direct Costs	60,820
Indirect Costs	0
Total Estimated Cost:	$60,820

*The total estimated budget includes the cost of investigating four pathogens: E. coli 0157:H7, L. monocytogenes, C. jejuni and S. aureus. If the agency (American Meat Institute) cannot support the total estimated cost ($60,820), $4,000 can be deducted for deleting studies on S. aureus, $8,000 can be deducted for deleting studies on S. aureus and C. jejuni and $12,000 can be deducted for deleting studies on S. aureus, C. jejuni and S. typhimurium.

The agency does not support indirect costs.

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March 9, 1993

Honorable Larry E. Craig
U. S. Senate
302 Hart Senate Office Building
Washington, D.C. 20515

Dear Senator Craig:

During my testimony before the Senate Agriculture Committee on February 5, 1993, you noted the absence of a page citation for one of my references to the National Academy of Sciences report, Meat and Poultry Inspection: The Scientific Basis of the Nation's Program.

Beginning on page 158, the report discusses Building Toward An Optimal System, Current Constraints. On page 159, the report states,

"On the basis of discussions with USDA personnel and a survey of inspectors and inspection facilities, the committee believes the difficulty in defining the FSIS mission, combined with the necessity to make multiple regulatory decisions, reduces the opportunity and the incentive for a comprehensive analysis. Even if objectives could be better defined and program officials were more cognizant of the need to step back and evaluate methods, other constraints must also be overcome to improve the decision process. Foremost among these are:

0 the tendency to continue to define health, aesthetic, or economic objectives in terms of visible pathology, rather than recognizing the changes that have occurred in both the makeup of the food supply and the hazards likely to be present;

0 the orientation of FSIS more toward the meat and poultry industry as its peer group than toward the broader scientific and public policy communities; and

0 the lack of sufficient scientific and technical commitment from the research components of USDA or of assistance from the university community to help FSIS address major technical problems."
(NAS, p 159, emphasis added)

I also reread the passage you cited from page 151 regarding the maximum use of producer certification. I took that to be a description of what the committee believed could occur in the future if a quantitative health risk assessment system were created

noting that the present system discourages an industry-wide ethic that producers and processors should be responsible for their products. I've attached copies of the pages to this letter.

You also inquired about statements I attributed to Russell Cross of the FSIS regarding when meat is contaminated. I believe the question relates to paragraphs at the bottom of page five of my printed statement. The quotes were taken from the Administrator's statement before the Washington State Senate and a memorandum he wrote to the Secretary on January 22, 1993. I have enclosed copies of both statements with the comments cited outlined. I believe my written statement accurately reports both.

Dr. Cross and I have a basic disagreement on this point. First, I do not believe his interpretation of the 1974 decision reflects the view of the Court. Second, if you choose to accept Dr. Cross's interpretation, the Department is still free to ask Congress to change the law. USDA has not done so. I believe it should. Third, I think it is inappropriate to label raw meat and poultry as "wholesome" when they contain pathogenic bacteria. The products may be rendered wholesome at a later time by cooking, but at the time USDA affixes the seal, they are contaminated. This is misleading.

I hope that these documents address satisfactorily the concerns you raised at the hearing. I will be happy to meet with you to discuss this issue or other matters relating to meat and poultry inspection.

Sincerely,

Carol Tucker Foreman

Enclosures

NEWS

United States Department of Agriculture | Office of Public Affairs | News Division Room 404-A Washington, D.C. 20250

Release No. 0092.93

Patricia Wagner (202) 720-7943

Testimony

by
DR. H. RUSSELL CROSS
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture

Before the State of Washington
Senate Committee on Agriculture

February 2, 1993

Madam Chairwoman, I am Dr. H. Russell Cross, Administrator of the U.S. Department of Agriculture's Food Safety and Inspection Service. With me is my assistant, Dr. Jill Hollingsworth. We very much appreciate the opportunity to be here today.

Before I begin, I want to reinforce the comments made by the secretary. We send our condolences to all family and friends affected by this tragedy. I also want you to know that the employees of FSIS are committed to pursuing every avenue to identify, contain and resolve this E. coli outbreak.

First, I will discuss what FSIS does. This agency is charged with inspecting meat and poultry products distributed in commerce to ensure they are safe and accurately labeled. FSIS carries out these inspections under the authority of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

We have 7,000 employees located throughout the United States inspecting meat and poultry. If a meat or poultry product is to be prepared at federally inspected establishments and/or distributed in commerce, an FSIS inspector inspects that product. Under the FMIA and the PPIA, we inspect the live animals before slaughter, and we inspect the carcasses after slaughter. Approximately 19 different inspection tasks are performed on each meat carcass.

As of the end of Fiscal Year 1991, 6,400 meat and poultry slaughtering and processing establishments received daily federal inspection. Over 117 million meat animals and over 6 billion birds were federally inspected during that year. Of the meat animals inspected during FY91, approximately 386,000 carcasses, or 1/3 of 1 percent, were condemned. For poultry, 75 million birds were condemned, or just over 1 percent. Carcasses are condemned for disease, contamination, or other adulteration during inspection.

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Inspections of imported meat and poultry from approved countries are also performed by FSIS at 210 import inspection establishments located at borders or ports. In 1991, approximately 2.5 billion pounds of imported meat and poultry were passed for entry into the United States. Approximately 12 million pounds, or less than 1 percent of imported product, were refused entry to the U.S. due to failure to meet Federal requirements.

Another part of our food safety program involves laboratory analysis. Inspectors in the field are supported by laboratory testing for chemical and antibiotic residues, pathology diagnostics, processed product composition, and economic adulteration. We also analyze cooked meat and poultry products for microbiological contamination.

To conduct these laboratory analyses, FSIS operates three multidisciplinary laboratories and two contract laboratories, and accredits 215 private laboratories. We also have laboratories located at the Beltsville Agriculture Research Center, which are methods development laboratories in pathology and microbiology. During Fiscal Year 1991, over 2.1 million analyses were performed on 470,573 samples at a cost of approximately $8.5 million.

Rapid in-plant screening tests provide another measure of safety. Results from these tests are available very quickly, thus assisting inspectors in making rapid food safety determinations about the product. Regrettably, there is no in-plant test developed and approved for microbiological testing of raw meat and poultry products. This is one of our highest research priorities and we expect significant progress in this area in the future.

FSIS also conducts enforcement and compliance activities to ensure that meat and poultry products in commerce are not adulterated, and are accurately labeled. In FY91, 63,416 compliance reviews were conducted. As a result of these reviews and other compliance activities, over 16 million pounds of meat and poultry were detained for noncompliance with meat and poultry laws. Twenty-nine recalls were conducted involving over 1.8 million pounds of product. In addition, 35 convictions were obtained against firms and individuals for violations of the FMIA and the PPIA.

The definition of "adulterated" under the meat and poultry acts has been construed by the Court of Appeals for the District of Columbia in American Public Health Association v. Butz, 511 F.2d 331 (D.C. Cir. 1974). In that case, the Court held that the presence of bacteria in raw meat and poultry does not constitute adulteration under the authorizing legislation. The Court has stated that Congress did not intend the prescribed official inspection legends on meat and poultry products to mean that the products were free from salmonellae and other bacteria because Congress did not intend that inspections include "microscopic examinations."

[For this reason, raw meat with pathogens, even this product with E. coli 0157:H7, is not considered adulterated.] Our review and investigation have shown that all of the meat implicated in this outbreak was inspected and met the federal criteria for "safe raw meat." The bottom line is that raw meat contains bacteria, but proper cooking kills bacteria.

Although FSIS doesn't routinely perform microbiological tests on raw meat and poultry products, we have begun a baseline data collection program. However, as I have stated, products inherently contain bacteria, which does not cause them to be adulterated under the law.

Even if our statutes were changed, science is not advanced enough to make rapid microbiological testing feasible. Nor does a sample give a true picture of all the product - it is not possible to know if the "right" product has been sampled unless everything is sampled.

The simple fact is that proper cooking of meat and poultry products kill harmful bacteria. Cooking for the proper amount of time and at the State-mandated temperature would have prevented this outbreak.

As you might imagine, however, simply saying "cook meat and poultry properly" is not a satisfactory answer. Although the inspection system did not fail, we want to do more. We will be working with the U.S. Congress to develop intermediate and long term strategies that will ultimately take us to an inspection system that takes advantage of emerging technology and focuses on the various risks found in meat and poultry -- including microbiological contaminants.

For the purposes of this hearing, I would like to focus on what we know today, what we can do today, and what we've already done.

FSIS was first notified by the Centers for Disease Control (CDC) of an outbreak of E. coli 0157:H7 in Washington State on January 18. In addition to immediately establishing a liaison with CDC, we contacted the State of Washington Department of Public Health to offer our assistance. We recognize that the Department of Public Health has the lead in this investigation, but we have offered our assistance in conducting microbiological testing and in exercising our authority in federally inspected meat plants that might be involved. We also made contact with laboratories and individuals identified by CDC as playing a role in this investigation. The Washington Department of Public Health traced the most likely source of the bacteria to undercooked hamburger patties served at Jack-in-the-Box restaurants.

The production date of November 19, 1992, has been implicated by the State of Washington as the product used by Jack-in-the-Box that contained E. coli 0157:H7. It has a "use by" date of March 19, 1993. We requested that all product marked with this "use by" date be held by the parent company of Jack-in-the-Box, Foodmaker. That day's production continues to be held and has been the subject of microbiological testing by the State of Washington, USDA, and CDC. Should any other production date be implicated, we will hold that product also.

On January 19, we sent a team of FSIS Compliance Officers to a warehouse owned by Foodmaker in Tukwila, Washington, which was identified as the distributor of hamburger patties to Jack-in-the- Box. Compliance Officers were on site to monitor the return of product to the warehouse from Jack-in-the-Box and to ensure that the hamburger patties were properly detained in freezers. As soon as we learned that product was also being returned to another Foodmaker warehouse in the City of Commerce, California, we also sent our Compliance Officers there to monitor the product detention.

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FSIS Compliance Officers have also been in touch with other state departments of health in states where the suspect product has been distributed. This includes the states of California, Nevada, Utah, Idaho, and Hawaii.

As you all know by now, the raw patties distributed by Foodmaker were produced at Vons Meat, a federally inspected establishment in El Monte, California. Vons grinds the meat and makes the patties for Foodmaker. For November 19, 1992, we have been told all the product went to Foodmaker.

FSIS has dispatched a microbiologist and an epidemiologist to Vons to collect environmental and product samples. We also have sent FSIS Inspection Operations personnel to Vons to examine records and trace back possible sources of meat Vons used in its production. The samples we have collected from Foodmaker represent the production lots produced at Vons on November 19, 1992.

FSIS has confirmed laboratory results from 4 of the sampled lots. The actual number of bacteria found have been relatively low. We are continuing our lab tests and will conduct well over 1,000 analyses.

The positive test results from the November 19 product from Vons now leads our investigation to the plants that supplied meat to Vons, not only on November 19, but from October 1, 1992, to the present. It is difficult to recreate conditions and events that existed on November 19, but we are checking records to see if we can further track implicated product, trying to determine where the bacteria came from and how it got into the product.

For each supplier of Vons, we have sent Inspection Operations personnel to examine current sanitation records and general operating procedures. We are also focusing on the records of each of the suppliers to see if any breakdown in normal procedures occurred around the suspect date.

In addition, microbiologist teams will be taking samples from every supplier plant. At these supplier plants, we will be performing product sampling in addition to record checks. As with Vons, it is very difficult to recreate conditions as they existed months ago at these plants, but we want to cover every base possible.

While we continue our investigation on all fronts, there are other things FSIS is doing. We will expand our microbiological baseline data collection in beef animals. This survey will be ongoing. Results will give us the opportunity to establish the kind and amount of bacteria that are present today, and to determine if future changes in inspection procedures improve the microbiological profile of the carcasses.

We have held briefings for consumer and trade groups and Congressional staffers to make them aware of this outbreak and to let them know of the steps we are taking to end it. We have issued numerous consumer publications on how to safely cook, handle and store meat and poultry products. We are happy to make those available to anyone needing this type of information. We also operate a toll free Meat and Poultry Hotline that is staffed by home economists who answer basic or technical questions about food safety. Our Hotline number is 1-800-535-4555.

-more-

Although most of our inspectors and indeed most of our employees know of this E. coli outbreak, we issued an alert to all inspectors yesterday calling their attention to possible sources of this bacteria. Specifically, we are asking our inspectors to review all operations and procedures at the establishments they inspect to ensure that we are doing everything we can.

Additionally, the National Advisory Committee for Microbiological Criteria for Foods is meeting today. This Committee was formed in 1988, and has been extremely helpful to FSIS and the Secretary in making recommendations on controlling bacteria in the food supply. In light of this current outbreak, we have asked the Committee to take up the topic of E. coli 0157:H7 at its meeting today.

Other educational work on E. coli 0157:H7 is ongoing. It is frustrating to realize how little is really known about this pathogen. We are identifying experts and researchers to determine if there is any new scientific information available. We are working with our sister agency, the Animal and Plant Health Inspection Service, to ascertain what information it might have about the occurrence of E. coli 0157:H7 in animals on the farm.

We do know that the group of bacteria called Escherichia coli are normally found in the intestines of warm-blooded animals such as food animals or humans. It can be found in contaminated water, and raw milk. It is not known at what level or dose the pathogen becomes hazardous.

In 1982, a rare and more virulent strain, called E. coli 0157:H7, was identified as the cause of two outbreaks of human illness. Since that time, there have been other reported outbreaks. Sources of E. coli 0157:H7 have included raw meat, water, unpasteurized milk, and low-acid apple cider.

E. coli 0157:H7 does not cause illness in animals. It can be carried in the intestinal tract of an animal, although it can also be found on the animal from contact with feces, and in the milk of dairy cows. Animals carrying this bacteria appear normal at the time of FSIS inspection, which is performed on each and every carcass. We do not know if the bacteria can be found elsewhere, such as circulating in the blood or lymphatic system. It can be transferred to the meat from the feces or milk. If there is any visible contamination on the meat, FSIS requires its removal. Also, all carcasses are thoroughly washed after inspection.

I cannot adequately express how distressed we in FSIS are that these tragic deaths and illnesses have occurred. But the fact is: bacteria, including pathogens, can be found on raw meat. This product is not adulterated. Science is not advanced enough to permit us to rapidly identify or control microbiological contaminants on raw meat, but E. coli 0157:H7 can be controlled by thorough cooking of raw meat.

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PUBLIC CITIZEN LITIGATION GROUP
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WASHINGTON, D. C. 20036
(202) 833-3000

February 2, 1993

MEMORANDUM

To: Pamela Gilbert, Director
Public Citizen Congress Watch

From: David C. Vladeck

Re: Comments on January 22, 1993 Cross Memorandum
On the Outbreak of E. coli 0157:H7 in Washington State

You requested that I review a January 22, 1993 memorandum from H. Russell Cross, Administrator, Food, Safety and Inspection Service, Department of Agriculture, which deals with the outbreak of E. coli contamination in Washington State. More specifically, you asked my opinion about Dr. Cross's discussion of the ramifications of American Public Health Association v. Butz, 511 F.2d 331 (D.C. Cir. 1974)("APHA"). Dr. Cross's memorandum asserts that the APHA court held that "the presence of bacteria in raw meat and poultry does not constitute adulteration under the authorizing legislation," and that "Congress did not intend the prescribed official inspection legends on meat and poultry products to import a finding that the products were free from salmonellae and other bacteria in that Congress did not intend that inspections include 'microscopic examinations.'" Cross Memorandum, at 1.

Having carefully reviewed the Court's opinion in the APHA case, and based on my knowledge and experience in this area, I am concerned that Dr. Cross's memorandum may be construed to suggest that the APHA ruling (a) disables the USDA from using microscopic and other modes of analysis to determine the extent of salmonellae and bacterial contamination in meat and poultry and from setting microbial standards for raw meat and poultry, and (b) the presence of a rare bacterial strain in meat or poultry does not render the food product adulterated.

Neither of these conclusions is warranted. The APHA case does not suggest that the USDA may not perform whatever technical analysis it believes is warranted to detect salmonellae and bacterial contamination. Nor does it forbid the USDA from concluding that meat or poultry contaminated with a rare or dangerous bacteria, or containing an infective dose level of

bacteria, is adulterated. What is more, the opinion certainly leaves the USDA free to do what we have advocated for years: to set standards limiting the concentrations and strains of bacteria that may be present in meat and poultry products -- standards, which, if exceeded, automatically render the food product adulterated.

In order to place the APHA ruling in its proper context, it is useful to focus on the underlying issues in that case. APHA was a labelling case, not a challenge to USDA's inspection practices. The plaintiffs in the APHA case alleged that the official USDA labels that stated that the meat and poultry was "U.S. inspected" or "inspected for wholesomeness" might constitute misbranding, because the labels failed to adequately explain to the consumer that the product may contain organisms capable of causing food poisoning or infection which would multiply unless the product is properly handled and cooked. The plaintiffs also argued that the labels should contain proper instructions on how to minimize such risks. Both the Meat and Poultry Acts prohibit misbranding.

In addressing the plaintiffs' claim that the absence of a warning about the danger of salmonellae rendered the product misbranded, the Court focused on whether the presence of salmonellae and other bacteria made the product "adulterated" under the Meat and Poultry Acts. To answer that question, the Court examined the definition of adulteration, which is common to both Acts, and which defines the term as covering poisonous, deleterious or harmful additives and filthy or decomposed substances. A product is not considered "adulterated," however, if the deleterious substance does not "ordinarily" render the food product injurious to health.

The Court found that the presence of salmonellae in meat or poultry does not necessarily make them adulterated per se for two reasons. First, the Court suggested, but did not hold, that the adulteration provision did not apply to substances such as salmonella which may be inherent in the meat or poultry. Second, the Court noted that, if proper food handling and preparation procedures are followed, salmonellae does not "ordinarily" render food injurious to health. In reaching this conclusion, the Court credited the Agriculture Department's claim that "the American consumer knows that raw meat and poultry are not sterile and, if handled improperly, perhaps could cause illness." APHA, 511 F.2d at 334. The Court also pointed out that the presence of salmonellae or other bacteria can be detected only by microscopic examination. The Court noted, as the plaintiffs conceded, that it would be physically impossible for inspectors to perform microscopic examinations for each of the 10,000 birds poultry

inspectors might examine each day.[1]

Given the narrow focus on the APHA decision, the implication in Dr. Cross's memorandum goes well beyond either the holding or dictum of the Court's ruling. To be sure, the Court recognized that the USDA could not be required to perform microscopic examinations on every single bird or every piece of beef inspected. However, nothing in the Court's opinion closes the door on substantial efforts by the agency to use microscopic, and any other technical tools that might be available to it, to detect salmonellae or bacteria in food products. Indeed, consumer organizations have long advocated that USDA step up its monitoring activities.

Nor did the Court hold that salmonellae or bacterial contamination could never make a food product adulterated. Surely, if USDA inspectors detected the presence of salmonellae or E. coli in concentrations or in strains that would ordinarily render the food product injurious to public health, then the product could be subject to the adulteration provisions of both the Meat and Poultry Acts. Equally important, the Court's opinion leaves USDA free to determine the amount of bacteria that would constitute an infective dose and would accordingly render it injurious to health -- and thus subject to the Meat and Poultry Act's adulteration provisions. Finally, nothing in the opinion casts the slightest doubt on USDA authority to set standards restricting bacterial contamination, which, if exceeded, would automatically render a food product adulterated.

To place this discussion in the context of the outbreak of foodborne contamination in Washington State, there are a few basic points. To begin with, there is simply no reason why the USDA inspectors at the Vons Meat Company plant that packed the Jack-in-the-Box hamburger could not have pulled out samples to analyze by microscopic and other technical means. Dr. Cross's memorandum appears to suggest that such testing is not ordinarily performed. Cross Memorandum, at 2. If that is the case, the USDA's lack of vigilance is regrettable. Nonetheless, had such testing occurred, it is possible that this particularly dangerous strain of E. coli would have been identified. In that event, the USDA would have had the opportunity to consider whether meat containing this rare

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[1] Judge Robinson dissented from this aspect of the Court's ruling, and would have remanded the plaintiffs' claim for a trial. Judge Robinson found that the idea that most consumers are knowledgeable about the risks posed by salmonellae and other bacteria "is a debatable proposition," and noted that the record "contains fact supporting appellants' assertion that people are not generally aware of the danger of salmonellae, much less of the safeguards required to avoid salmonellosis." APHA, 511 F.2d at 336 (Robinson, J., dissenting).

strain of E. coli is adulterated under the Meat Act, in that it presents an unreasonable risk to health, particularly since, insofar as I am aware, meat must be cooked at a very high temperature for an unusually long period of time to destroy the bacteria. Had USDA proceeded in this manner, perhaps this public health crisis could have been averted.

If you have any further questions, please let me know.

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February 4, 1993

BY HAND

Ms. Carol Tucker Foreman
Safe Food Coalition
c/o Foreman & Heidepriem
Suite 750
1112 Sixteenth Street, N.W.
Washington, DC 20036

Dear Carol:

In the wake of the recent food poisoning tragedy involving USDA-inspected meat products in the state of Washington, questions have again arisen as to the authority of USDA to promulgate standards with respect to bacterial contamination of raw meat and poultry and to treat meat and poultry that fail to meet those standards as adulterated. Specifically, the argument continues to be made that a 1974 decision by the U.S. Court of Appeals for the D.C. Circuit in American Public Health Association (APHA) v. Butz, 511 F.2d 331, stands as a legal barrier to USDA treating bacterially-contaminated meat and poultry as adulterated within the meaning of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

You have asked whether the APHA decision in fact precludes USDA from establishing standards for bacterial contamination and finding noncomplying meat and poultry to be adulterated within the meaning of the FMIA and PPIA. For the reasons discussed below, I conclude that it does not. USDA is free, on appropriate factual findings, to determine that meat or poultry that does not meet standards limiting the amount of harmful bacteria present in the meat or poultry is adulterated within the meaning of the statutes and therefore may not lawfully be sold.

Under Section 1(m)(1) of the FMIA, 21 U.S.C. § 601(m)(1), meat is adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance,

such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health." Section 4(g)(1) of the PPIA, 21 U.S.C. § 453(g)(1), contains the same definition.

The APHA case did not involve the issue of adulteration as such, but rather the question whether, given the risk of bacterial contamination, meat and poultry should be deemed misbranded under the FMIA and the PPIA unless labeled with warnings to consumers about the possible presence of bacteria and directions for cooking and handling to assure safe use. A closely-divided court[2] held that regardless of whether bacterial contamination were viewed as rendering raw meat or poultry adulterated, USDA could reasonably conclude that the meat or poultry was not misbranded, even in the absence of any warning or directions for use. The court upheld USDA's exercise of discretion to determine that a general consumer education campaign was preferable to a labeling requirement.

To be sure, the court did state that "we think that the presence of salmonellae in meat does not constitute adulteration within this definition." 511 F.2d at 334. The court apparently accepted the Department's reasoning that because consumers are generally aware that proper handling and cooking of raw meat and poultry will eliminate the risk of illness from salmonella, the bacteria, as a naturally occurring contaminant, should not be regarded as "ordinarily" rendering the meat or poultry injurious to health. The court assumed that salmonella was an "inherent" contaminant subject to the more-difficult-to-show test of "ordinarily" rendering the product injurious to health rather than an "added substance" subject to the "may render" test.

A few years later, however, the same court of appeals characterized these statements about adulteration in APHA as dictum. Continental Seafoods, Inc. v. Schweiker, 674 F.2d 38, 41 (D.C. Cir. 1982). There the court, applying a similar definition of "adulteration" in the Food, Drug, and Cosmetic Act, found that the APHA decision did not preclude FDA from treating salmonella as a substance that was "added" to shrimp and finding the salmonella-contaminated shrimp to be adulterated. See also Seabrook National Foods, Inc. v. Harris, 501 F Supp. 1086, 1092 (D.D.C. 1980).

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[2] The court was divided 2-1; Judge Robinson dissented, and was joined by two other judges (Bazelon and Wright) in voting for rehearing en banc. While rehearing was denied, Judge Leventhal, as discussed below, emphasized his view that USDA could take action if factual developments warranted.

In any event, the APHA court's statements with respect to adulteration were based on its acceptance of the factual premises of the Department at that time (more than 18 years ago) -- factual premises relating to the state of knowledge of American consumers about proper methods of preparing and cooking food. The court may also have been influenced by the unavailability of practical methods for detecting the presence of bacteria during the inspection process. Nothing in the APHA decision suggests that USDA is not free, upon appropriate findings, to conclude that the human health risk presented by the presence of bacteria in raw meat and poultry is sufficiently serious to render such products "ordinarily injurious to health."[*] USDA, as the expert agency charged with administration of the FMIA and the PPIA, may take into account, for example, evidence that significant numbers of consumers are unaware of the cooking and handling precautions necessary to avoid the risk of illness; that such precautions are in any event often not followed (e.g., when the restaurant customer orders his hamburger "rare"); that the presence of bacteria is more common than previously thought; or that the ability to detect their presence has improved. Indeed, Judge Leventhal, in an opinion explaining his vote to deny rehearing en banc of the APHA decision, expressed his doubts about the Department's ability to educate consumers and cautioned that the court's decision did not "preclude a new challenge if it develops that consumer education programs prove inadequate to provide realistic protection." 511 F.2d at 338.

In short, the APHA decision stands at most for the proposition that USDA, on the factual record as it existed in 1974, was not required by the statute to treat bacterially-contaminated meat and poultry as adulterated. The decision in no way limits the Department's authority, upon appropriate findings,

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[*] Nor does the decision preclude USDA from concluding, if there is a factual basis for such a finding, that there is sufficient human intervention in the process that leads to E-Coli or other bacterial contamination to treat such bacteria as "added substances." If USDA so found, a conclusion of adulteration would readily follow. For there can be little doubt that significant amounts of E-Coli "may render" the meat or poultry "injurious to health."

to establish standards for bacterial contamination and to treat products not meeting those standards as adulterated.

Please let me know if you have additional questions.

Sincerely,

Daniel Marcus

Daniel Marcus

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

to be sampled with 56 proc plants 7 combo plants

JAN 22 1993

INFORMATION MEMORANDUM FOR THE SECRETARY

FROM: H. Russell Cross
Administrator

SUBJECT: Outbreak of E. coli 0157:H7 in Washington State

ISSUE:

At 5:00 PM on Monday, January 18, FSIS was notified by the federal Centers for Disease Control (CDC) in Atlanta, GA of an alleged outbreak of E. coli 0157:H7 in Washington. FSIS immediately established contact with the CDC and Washington State Department of Public Health to offer assistance and has been actively involved in the investigation.

Washington officials have told us that there are as many as 100 suspected cases of foodborne illness and one death. Similar cases are also being reported from Idaho and Nevada. Preliminary information also suggests that foodborne disease cases are either currently being reported from the San Diego, CA area, or that there has been a previous outbreak in December in that area.

Background

The Food Safety and Inspection Service (FSIS) carries out its responsibilities under the Federal Meat Inspection Act and Poultry Products Inspection Act. FSIS would not be involved in the epidemiological investigation of a foodborne outbreak until such time as we were notified that an inspected meat or poultry product might be implicated.

The Court of Appeals for the District of Columbia has held that the presence of bacteria in raw meat and poultry does not constitute adulteration under the authorizing legislation. The Court stated that Congress did not intend the prescribed official inspection legends on meat and poultry products to import a finding that the products were free from salmonellas and other bacteria in that Congress did not intend that inspections include "microscopic examinations." American Public Health Association v. Butz, 511 F.2d 331 (D.C. Cir. 1974).

Bacteria that can cause human illness, called pathogens, are normal inhabitants of the digestive tract of animals. These bacteria are not visible and therefore can not be detected by normal inspection procedures. Animals with E. coli 0157:H7 show no unusual symptoms and do not get sick from the bacteria. There are no rapid, in-plant tests available to determine if animals are infected with E.coli 0157:H7. This specific strain of bacteria is very difficult to isolate and its occurrence is considered rare.

E. coli 0157:H7 is destroyed by heat and raw meat containing this bacteria will be safe to eat if properly cooked. The Food and Drug Administration provides uniform codes for cooking temperatures for raw meat and, in this specific case, the state of Washington has a cooking requirement more stringent than the FDA code.

Meat is not the only source of E. coli 0157:H7, but when it is incriminated as the source in an outbreak , it is most often associated with undercooking of raw product.

FSIS Response

When FSIS was notified by CDC of the outbreak, the State of Washington Department of Public Health had the lead in the epidemiological investigation, assisted by the CDC. This was the appropriate action. FSIS offered microbiological assistance and started closely tracking the investigation so that we would be prepared to proceed with our action if a link to a meat product was confirmed by the investigators.

The state epidemiologist informed FSIS that their investigation had determined that the most probable source of the outbreak had been traced to undercooked beef patties served at several Jack-In-The-Box fast food restaurants.

On January 19, an FSIS Compliance Officer was dispatched to the warehouse that was identified by the state as the distributor of the raw hamburger patties. The state was working closely with the distributor and parent company of Jack-In-The-Box, Foodmaker, Inc., to identify and recall suspect product. The FSIS compliance officer is at the warehouse to ensure that the product is retained and confined.

The raw hamburger patties were produced at Vons Meat, a federal establishment in El Monte, Ca. Federal inspectors are routinely at this plant on a daily bases. The state investigators suspect at this time that the source product was produced on one day, November 19, 1992 and is all coded with a "use by" date of March 19, 1993. FSIS inspectors have coordinated with the management of Vons Meats to determine the distribution of all raw hamburger patties produced on that day and to ensure the recovery of any remaining product.

FSIS is dispatching personnel from its Emergency Programs Staff and Microbiology Division to Vons Meat to continue its investigation and to collect environmental samples for laboratory analysis. In addition, samples of the raw hamburger patties being held at the Foodmaker warehouses are being collected and sent to the USDA laboratory in Beltsville, Maryland for analysis.

FSIS inspectors are further tracking the source of the raw patties back to the suppliers. Once they are identified, FSIS will conduct reviews at these plants to ensure proper procedures are in place.

Although the state authorities suspect that the hamburger patties coded March 19 is the source, FSIS has decided to hold all the product recovered from the Jack-In-The-Box restaurants currently at the Foodmaker Warehouses.

FSIS microbiologists continue to work closely with the state, CDC, and private labs that are all involved in testing samples.

Other Considerations

Under current regulations, the presence of bacteria in raw meat, including E. coli 0157:H7, although undesirable, is unavoidable, and not cause for condemnation of the product. Because warm-blooded animals naturally carry bacteria in their intestines, it is not uncommon to find bacteria on raw meat.

Given the difficulty associated with isolating this particular strain of bacteria, it is possible that no positive laboratory confirmations will be made. FSIS will be faced with determining what to do with the raw patties both with or without laboratory confirmation.

To date all product is being held based on epidemiological evidence and investigation but not on laboratory findings. FSIS has been in close contact with the companies involved and believe that an appropriate course of action can be taken. Options include:

- the company voluntarily condemning all product under FSIS supervision;

- all suspect product being cooked at a federal establishment under FSIS supervision.

Facts About E. coli 0157:H7

Escherichia coli are a group of bacteria found in the intestines of warm-blooded animals and humans. They can cause intestinal illness, especially diarrhea. In 1982, a rare and more virulent

strain, called E. coli 0157:H7, was identified as the cause of two outbreaks of human illness. Since that time, there have been several reported outbreaks.

E. coli 0157:H7 does not cause illness in cattle and animals carrying this bacteria appear normal during inspection examinations. There are no rapid, in-plant tests for detecting this bacteria. FSIS has no way of knowing if raw product contains E. coli 0157:H7. However, testing for this bacteria has been included as part of the Agency's microbiological baseline sampling program and to date no positive samples have been found. E. coli 0157:H7 can be easily controlled by thorough cooking of raw meat.

E. coli 0157:H7 can be lethal, especially in small children, who can develop acute kidney failure from this infection. Illness from E. coli 0157:H7 at this time is not a reportable disease as defined by CDC.

FSIS has been active in research and data collection involving E.coli 0157:H7. Our sampling programs have proven that this is a very difficult bacteria to detect and its occurrence in raw meat and poultry is extremely low. FSIS has been in the forefront in developing methods to analyze and recover E. coli 0157:H7 from meat and poultry products.

FOOD RESEARCH INSTITUTE

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February 3, 1993

Senator Tom Daschle, Chairman
Subcommittee on Agricultural Research,
Forestry, Conservation, and General Legislation
United States Senate
Washington, DC 20510-6000

Dear Senator Daschle:

Thank you for your recent letter (February 1, 1993) inviting me to submit written testimony about the Federal food safety program and government regulation of coliform bacteria. After careful review of your letter and consultations with my colleagues at the Food Research Institute, my comments addressing your concerns are detailed below. Also, I have enclosed a concise and accurate fact sheet on Escherichia coli 0157:H7, the coliform bacterium incriminated in the current foodborne outbreak involving ground beef.

Pursuant to addressing your specific concerns, I will preface my remarks by stating that without question the United States maintains one of the safest food supplies in the world. This is due in large measure to our collective ability to produce, manufacture, distribute, and store foods properly. However, as evidenced by the recent outbreak of foodborne illness involving E. coli 0157:H7, these efforts are to no avail if raw foods are not properly cooked immediately prior to consumption.

As outlined in more detail in the accompanying fact sheet, both the incidence (<4%) of E. coli 0157:H7 in ground beef and the number of outbreaks involving this bacterium (2 per year; 25-70 people per outbreak) are low. Moreover, the bacterium is fairly heat sensitive. Cooking ground beef to an internal temperature of 155°F for as little as 5 seconds and 12 seconds produces a 3-log and 7-log decrease in viable E. coli, respectively. It must be emphasized that as raw products, beef and poultry harbor high numbers of bacteria, a small component of which may be illness-causing. It would indeed be an enormous undertaking to screen all raw products for the presence of pathogenic bacteria, with very little benefit derived. Likewise, screening raw products would not necessarily eliminate pathogens from the food supply (i.e., it is not practicable now or in the foreseeable future to certify raw foods as pathogen-free at the wholesale or retail level). Knowing pathogenic bacteria are present in raw food, and assuming surveillance measures would substantiate their presence, does not mean the raw food would be unfit for human consumption if it is intended to be properly stored and thoroughly cooked before it is eaten.

Current microbiological methods for detecting pathogens in foods including E. coli 0157:H7 are often costly, tedious, and time-consuming (e.g., 1-2 days for a presumptive positive, and at least 3-5 days for confirmation at a cost of about $50 per test). Even then, there is no guarantee that the organism is absent from all portions of the meat. The impact on industry and consumers would be considerable, as the cost of beef and poultry would increase substantially while products were held pending the results of microbiological analyses. In this regard, I concur in principle with the assessment made by USDA's Food Safety and Inspection Service and the Food and Drug Administration that the HAACCP system is the most effective strategy for controlling pathogens in the food supply. Although I am not in possession of the detailed HAACCP strategy for the Federal food safety program, I do have an understanding and appreciation of HAACCP principles. As such, the application of HAACCP systems, particularly at slaughter, are most beneficial for diminishing the likelihood of pathogen presence, but it will not guarantee their absence. Thus, it would seem more prudent to invest dollars and manpower to increase public awareness of the importance of cooking and storing foods properly and to further educate the public about food safety. It would also seem important to focus research funds/efforts to expand upon work initiated/ongoing at the Food Research Institute and other appropriate laboratories. We badly need better methods to detect, enumerate, type, and control E. coli 0157:H7 associated with foods. We also need to expand our understanding of the occurrence and dissemination of the pathogen in the environment, notably in cattle.

I hope my comments and the specific information about E. coli 0157:H7 will be of use to you and the Subcommittee. Please contact me if questions arise or if I can be of further assistance.

Sincerely,

Michael W. Pariza

Michael W. Pariza, Ph.D.
Director and Chair
Wisconsin Distinguished Professor

MWP:mkr

Enclosure

(Signed for Dr. Pariza
by E. M. Foster, Ph.D.
Emeritus Director

ISSUE: *Escherichia coli* (*E. coli*) serotype 0157:H7

E. coli is a common bacterium found in the intestinal tracts of man and animals. Although most *E. coli* are harmless, some are human pathogens, including *E. coli* 0157:H7. This specific serotype has several distinguishing characteristics compared to other *E. coli*, notably the inability to ferment sorbitol, the absence of ß-glucuronidase activity, and the inability to grow at 45.5°C. Virulence of the organism is attributed, in large measure, to the production of toxin(s) (i.e. VT I and/or VT II). *E. coli* 0157:H7 has only been recognized as a foodborne pathogen since 1982. The primary reservoir is cattle and the most frequently implicated foods are ground beef and raw milk. The pathogen has also been identified as a causative agent of hemorrhagic colitis[1]. From 10-15% of the individuals with 0157:H7 hemorrhagic colitis - mostly children and the elderly- will develop hemolytic uremic syndrome (HUS)[2]. Progression of the infection may also lead to thrombotic thrombocytopenic purpura (TTP)[3], a condition similar to HUS but involving the central nervous system. Due to its presence in raw foods and the potential severity of illness and attendant costs, studies to expand our understanding of *E. coli* 0157:H7 remain active and essential areas of research.

E. coli 0157:H7 facts:

* Dairy cattle are thought to be the major reservoir.
* Most cases have been linked to undercooked ground beef and to a lesser extent unpasteurized milk.
* Slaughter practices are thought to be the point of contamination.
* Incidence in retail meats is low; 3.5% ground beef, 2.0% lamb, 1.5% pork, and 1.5% poultry; USDA, FSIS study found *E. coli* 0157:H7 in two samples of 1668 samples of raw ground beef and ground veal.
* It is **not** unusually heat resistant and is killed by typical times/temperatures used to kill other bacterial pathogens (i.e. salmonellae).
* It survives but does **not** grow in the refrigerator (4°C) or freezer (-20°C).
* Current testing methods require a minimum of 26 hours to determine its absence in foods; however, an additional 3-5 days are needed for confirmation of presumptive positive isolates.

[1] Characterized by abdominal cramps and bloody diarrhea.
[2] Symptoms include anemia, thrombocytopenia, and renal failure.
[3] Progression of HUS symptoms plus involvement of central nervous system.

AMI AMERICAN MEAT INSTITUTE
Serving The Industry Since 1906.

J. Patrick Boyle
President and C.E.O.

February 3, 1993

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
14th Street and Independence Avenue, SW
Washington, DC 20250

Dear Mr. Espy:

As the representative of 90 percent of the nation's meat and poultry industry, the American Meat Institute (AMI) is deeply saddened by the recent food borne illness outbreak associated with undercooked hamburger in the Northwest.

We are also saddened by the opportunists who now seek to transform this human tragedy into a misdirected public debate about meat and poultry inspection. As you and FSIS officials have repeatedly noted, no inspection system can completely eliminate pathogens from raw meat and poultry. Thus, part of the responsibility for safe food rests on food handlers and preparers to cook and serve meat and poultry properly.

The federal government's own statistics show the source of most food borne illness outbreaks is clearly not food processing companies; rather, it is improper food handling. The Centers for Disease Control (CDC) reports that 77 percent of all traceable food borne illness outbreaks result from improper handling or cooking at food service establishments.

This recent outbreak sheds light on a nationwide problem: inconsistent information about proper cooking temperatures for hamburger. Only one of 50 states has a hamburger cooking requirement of 155 degrees Fahrenheit. Yet the meat industry has had 155 degree cooking guidelines for pre-cooked hamburger patties since 1989 and we have experienced no food borne illness incidents with pre-cooked hamburger patties since.

Accordingly, we would urge the department to take the following three steps:

First, Mr. Secretary, we urge you to adopt immediately the meat industry's existing guidelines for the microbiological safety of pre-cooked hamburger patties. We are urging Secretary of Health and Human Services Donna Shalala to take the same action on behalf of the Food and Drug Administration (FDA), and we will ask all state health departments to adopt these guidelines for commercial hamburger cooking establishments as well.

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Phone: 703/841-2400 Fax: 703/527-0938

Following these guidelines, which stipulate cooking hamburger patties to 155 degrees Fahrenheit, is the only guarantee that *E. coli 0157:H7* will not survive and will not cause further outbreaks traced to hamburger.

Secondly, we urgently request that you and Secretary Shalala appoint a joint-agency task force to oversee much-needed research into the origin of and the critical control points for eliminating *E. coli 0157:H7*. This research is desperately needed and should be overseen at the highest possible levels. In addition, we offer industry resources to participate in or contribute future research efforts.

Thirdly, we recommend that you convene as soon as possible a meeting of the National Advisory Committee on Microbiological Criteria for Foods. This advisory committee is comprised of industry, academic and government food safety experts and is co-chaired by USDA and FDA. We believe that the committee members' collective expertise may be of major assistance to FSIS as the agency reviews its microbial monitoring programs.

In conclusion, the entire food production and handling continuum -- from farm to table -- has an obligation to produce safe foods that do not cause food borne illness. As meat and poultry packers and processors, we willingly bear part of that responsibility. We are committed to producing the safest meat and poultry products in the world and pledge our support for the research and education necessary to reduce food borne pathogens.

Sincerely,

J. Patrick Boyle

CNI
Community Nutrition Institute 2001 S Street, N.W., Suite 530 Washington, D.C. 20009 (202)462-4700

February 1, 1993

Secretary Mike Espy
Department of Agriculture
12th and Jefferson Drive
Washington, D.C. 20250

Dear Mr. Secretary:

The death of a child and the severe illnesses of hundreds of other persons who consumed unfit meat served by a fast food company in the Northwestern United States is a public health disaster. It could have been avoided if the Department of Agriculture had been doing its job of protecting consumers. However, USDA has sought over the past 12 years under your predecessors to deregulate meat and poultry inspection, undermining the authority of inspectors in meat and poultry plants and to implement policies which have crippled the food safety shield called for by federal legislation.

The Department's response to this latest outbreak of food poisoning is to shift the blame to the fast food establishment for failing to cook the meat properly. If that is all that is required to insure wholesome food in the United States, then why do we need to spend a half billion dollars each year on a food safety shield to inspect meat and poultry?

The fact is that USDA has pursued a failed policy, and the Clinton administration must declare that food safety in the United States will be guided by a new commitment to public health. A new policy must emphasize a clean break with the past, and distinguish the Clinton administration from the policies of the Reagan-Bush administrations which have contributed to the collapse of the Nation's food safety shield.

The food safety goal of the Clinton administration must be to reduce bacterial contamination and to restore public confidence in meat and poultry by making food safe again. The Clinton administration must abandon the present goal of deregulating food safety. In 1989 the Safe Food Coalition proposed a series of recommendations for comprehensive reforms to genuinely modernize food inspection. They were ignored by the Bush administration. They are summarized and updated below:

The objectives of a new food safety policy must be to:

1. *Strengthen the field staff.* The inspection authority of inspectors in the field has been compromised by current policies, and must be restored. The food safety problem begins in the slaughtering and processing plants, not in cooking temperatures. The strategy of increasing top level bureaucracy insures that food safety needs in the field will go undiscovered and undetected, yet that has been the policy in the past. Disease conditions, unsanitary practices, lax hygiene must be detected early and eliminated quickly before the whole food system is compromised and contaminated. Only a vigilant force of inspectors in the field can protect the public interest in public health. Full inspection staffing in the field must be restored, and a bloated headquarter bureaucracy must be cut.

2. *Adopt a new USDA food safety policy:*

a. Publish a new mission statement committing top staff in headquarters and regional offices to support inspectors in the field;

b. Adopt a new designation for the meat and poultry inspection programs to emphasize the clean break with failed policies;

c. Bring in new leadership in the headquarter staff, and develop evaluation criteria for regional headquarter staff performance that emphasizes support of inspectors in meat and poultry plants, including the absence of retaliation against whistleblowers as a critical element;

d. Drop current plans to deregulate meat and poultry safety which "manage" the health crisis from the top. New policies must enhance field operations rather than substitute for field staff. Explicit whistleblower protection consistent with 1992 legislation should be extended to corporate employees;

e. Initiate a comprehensive training program to raise and sustain inspector skills.

3. *Develop microbiological standards for meat and poultry products, including testing requirements at different stages of meat and poultry production and distribution.*

4. *Develop a new food safety research program that would:*

a. Emphasize methods, procedures and technologies to enhance the ability of the field force to protect consumers from contaminated meat and poultry;

b. Provide rapid laboratory testing of samples of contaminated products;

c. Develop and recommend requirements for meat and poultry slaughter and processing that examines the synergistic effects of machines, technology and personnel in plants on contamination;

d. Develop and recommend new procedures and processes for controlling bacterial contamination based on the capacity of bacteria to adapt and survive chemical treatments, and to insure that the new methods and techniques will not have adverse health consequences;

e. Assign technology assessment responsibilities to USDA rather than industry;

f. Include whistleblower protection for those participating in the program.

The present public health crisis is an opportunity to distinguish the Clinton administration from the failed policies of its predecessors, and to fulfill the commitment of President Clinton to restore public faith and trust in a government dedicated to working for the people. The statement of goals and objectives that we have outlined is a place to begin the task of rescuing public health policy. Failure to do so now would be the same as endorsing the policies which the Clinton administration was elected to change.

We are eager to work with you and with the meat and poultry industry to start a new beginning in food safety policy.

Sincerely,

Rodney Leonard,
Community Nutrition Institute
For:

Pamela Gilbert,
Public Citizen's Congress Watch

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cc: August, 11, 1989 memorandum

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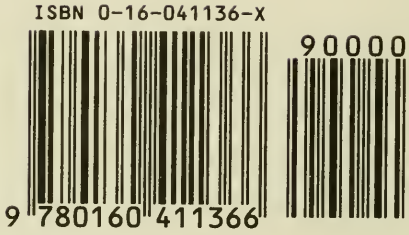

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